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National Animal Health Emergency Management System Guidelines

U.S. Department of Agriculture

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DRAFT

Operational Procedures Guidelines

Vaccination for Contagious Disease

Please Note: This document was originally designed for potential vaccine use in light of an incursion of Foot-and-Mouth disease (FMD) into the United States. While many aspects of this document are FMD-specific, it can be used as a general guide for vaccination for any contagious disease. The document is undergoing revision to provide more general advice for vaccine use.

The National Animal Health Emergency Management System Guidelines provide an operational framework for use in dealing with an animal health emergency in the United States.

The guidelines are produced by the Veterinary Services Unit of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

These guidelines are under ongoing review. Please send questions or comments to:

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Preface

"Vaccination for Contagious Disease," a component of APHIS' National Animal Health Emergency Management System (NAHEMS) Guidelines series, is designed for use Veterinary Services (VS) in the event of a major animal health emergency such as an incursion of a foreign animal disease into the United States. The NAHEMS guidelines may be used by any emergency animal disease eradication organization for integration into the preparedness plans of other Federal agencies, State and local agencies, Tribal Nations, and additional groups involved in animal health emergency management activities.

Topics covered in the guidelines include:

- Field investigations of animal health emergencies
- Disease control and eradication strategies and polices
- Operational procedures for disease control and eradication
- Site-specific emergency management strategies for various types of facilities
- Administrative and resource management
- Educational resources

The NAHEMS guidelines provide a foundation for coordinated national, regional, State, and local activities in an emergency situation. As such, they are meant to complement non-Federal preparedness activities. The guidelines are being reviewed and updated on an ongoing basis, and comments and suggestions are welcome.

"Vaccination for Contagious Disease" provides Vaccination Unit Leaders and associated personnel with guidelines for vaccination activities. The document is meant for use as a practical guide rather than as a comprehensive reference resource.

The general principles provided in the guidelines are intended to serve as a basis for making sound decisions. However, deviations from the guidelines may be permissible, if necessary, to address a given situation effectively. In addition, information provided in various sections may need to be combined to meet the requirements of a particular situation.

Acknowledgments

"Vaccination for Contagious Disease" reflects the efforts of a number of individuals, including an APHIS Veterinary Services (VS) Writing Group, additional APHIS staff members, and a wide range of reviewers. These reviewers include Federal and State Veterinarians, members of APHIS' animal health emergency response teams, officials of other Federal agencies, representatives of industry, and additional experts.

Also acknowledged with appreciation are the efforts of USDA staff and external reviewers involved with the development of the VS animal health publications ("red books") and similar documents that have served as information sources for the NAHEMS guidelines. The contributions of each individual are appreciated.

The Decision Tree Matrix in Chapter 2 was developed by representatives of Canada, Mexico, and the United States as part of a Tripartite Exercise 2000 program held in November 2000. The meeting was sponsored by the North American Animal Health Committee, which is composed of animal health officials from the three countries.

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1 Introduction

Please Note: **This document was originally designed for potential vaccine use in light of an incursion of Foot-and-Mouth disease (FMD) into the United States. While many aspects of this document are FMD-specific, it can be used as a general guide for vaccination for any contagious disease. The document is undergoing revision to provide more general advice for vaccine use.**

Implementation of an animal vaccination program for contagious disease as part of a national or regional eradication effort is a complex undertaking involving myriad considerations and decisions. These guidelines provide an overview of some of the key aspects of such a program, including the responsibilities of Vaccination Unit personnel; assembling and equipping a vaccination team; organizing and staffing a Vaccination Center; ordering, storing, and using vaccine; following effective on-premises vaccination procedures; and keeping accurate, complete vaccination records. The document also addresses vaccination issues such as whether and when to vaccinate, how to deal with owners who refuse to vaccinate, and ways to handle difficult animals.

The guidelines are meant for use as a practical field resource rather than as a comprehensive reference work. Additional information on FMD is available from sources such as the following:

- The APHIS home page (www.aphis.usda.gov; select "Foot-and-Mouth disease" under "Hot Issues" for a variety of FMD information sources and resources).

- APHIS' Centers for Epidemiology and Animal Health Web site (www.aphis.usda.gov/vs/ceah; perform a search using "vaccination" as a keyword).

- The United States Animal Health Association's "Foreign Animal Diseases" handbook (1998).

- Institutions of higher education and State agricultural extension services (e.g., the University of California, Davis, at www.vetmed.ucdavis.edu; select "Continuing Education," "Veterinary Extension," and "Animal Welfare;" the University of Nebraska, Lincoln, at www.unl.edu; click on "Cooperative Extension" and then on "Publications;" and Purdue University's National Biosecurity Resource Center for Animal Health Emergencies at www.biosecuritycenter.org.)

  The agricultural ministries or departments of other countries (e.g., the United Kingdom's Department for Environment, Food and Rural Affairs at www.defra.gov.uk; select "Animal Health & Welfare" and then "Animal Welfare"; Animal Health Australia's "Foot-and-mouth disease" manual at http://www.aahc.com.au; select "Emergency Animal Disease Preparedness," "AUSVETPLAN Development," and "Foot-and-mouth disease"; and the

Canadian Food Inspection Agency at www.inspection.gc.ca; select "English" and "Foot and Mouth Disease").

- Industry. Resources such as "FMD and the Dairy Industry's Emergency Preparedness" are accessible on the Dairy Response Center home page (www.dairyresponse.com).

The guidelines focus on essential areas such as the responsibilities of vaccination personnel, the vaccination center, the vaccine, the vaccination team, vaccination procedures, and keeping vaccination records. The document is designed for use not only in emergency situations but also in animal health emergency training programs. A brief overview of key elements of such programs is provided below.

Emergency Response Exercises

Well before an animal health emergency strikes, vaccination personnel should use the "Vaccination for Foot-and-Mouth Disease" guidelines in emergency response exercises designed to help them expand their knowledge of animal health emergency management. Such sessions will help learners identify likely emergency scenarios and develop detailed plans for responding to each scenario effectively.

The First 24 Hours—A useful assignment challenges participants to use the guidelines to create a detailed plan for the first 24 hours of an animal health emergency. Participants can use information in the guidelines to answer questions such as:

- What relationships with other key personnel, including individuals in the emergency management community, should be in place prior to the emergency?
- What key information and resources (e.g., equipment and supplies) need to be readily available, and where and how will they be obtained, stored, and accessed?
- What actions will need to be taken immediately? If these actions are not taken, what consequences are likely?
- What obstacles may appear and how will they be overcome?
- What conflicting pressures are likely, and how will they be balanced?
- If an initial plan fails, what are the elements of an effective alternative plan?

Evaluation—The evaluation phase of test exercises will provide participants with the opportunity to use the guidelines to (a) evaluate the strengths and weaknesses of their responses in the simulation exercises and (b) focus on ways to improve their response capabilities in the event of an actual animal health emergency. The exercises also will underscore the need for participants to develop and maintain strong collaborative relationships with their counterparts in the emergency management community.

Interagency Outreach

If the presence of an FAD or arthropod vector or other type of animal health emergency is identified in the United States, the appropriate local, State, and Federal Governments and their partners in the private sector (e.g., industry and academia) must respond in a coordinated, mutually supportive manner to (a) determine the nature of the outbreak, (b) initiate an appropriate response, (c) eliminate or control the disease, and (d) help facilitate recovery (e.g., resumption of trade). The NAHEMS guidelines are designed for use at any of three levels of response commensurate with the severity of the outbreak.

These levels include:

- *A local/limited response.* This level of response is managed by local, State, Federal, and industry officials, with response coordination provided primarily at the State and regional levels and with national-level consultation and consequence management (e.g., trade issues).

- *A regional response.* A regional response is managed by local, State, Federal, and industry officials—in some cases, with the involvement of the appropriate State emergency management agency as specified in State animal health emergency response plans. National-level crisis management, response coordination, consultation, and consequence management are required.

- *A national response.* This level of response requires the combined efforts of local, State, industry, and Federal agricultural officials as well as nonagricultural personnel from Government (e.g., the Federal Emergency Management Agency) and the private sector in national-level crisis management, response coordination, consultation, and consequence management.

Regardless of response level, the agricultural community must be prepared to work closely with the emergency management community to deal with an animal health emergency. The State-based, nationally coordinated Animal Emergency Response Organization (AERO) model addresses this need. The AERO model is based on the Incident Command System (ICS), an emergency response approach used widely in the emergency management community.

To promote the widest possible application and implementation of guidelines content, this publication refers to the titles of officials and groups based on the AERO/ICS model. It is hoped that this approach will help the reader understand the essential aspects of animal emergency response activities in terms of the model.

2 Responsibilities of Vaccination Personnel

Vaccination personnel provide services that are essential to an effective animal health emergency response, including the need to control and eradicate a foreign animal disease.

Key vaccination personnel include:

- The Vaccination Unit Leader, who plans and conducts the vaccination program in consultation with the Incident Commander(s), to whom he or she reports.

- Vaccination Team Managers, each of whom serves as leader for a Vaccination Team.

- Vaccination Team Members (made up of individual Vaccination Unit Members).

The Vaccination Unit Leader is based at the Incident Command Post, and each Vaccination Team works on multiple premises sequentially.

As an integral part of the overall animal health Animal Emergency Response Organization, the Vaccination Unit works closely with other units to ensure a smoothly functioning operation. The Vaccination Unit is based in the Operations Section.

All vaccination personnel should learn as much as possible about the procedures discussed in these guidelines and in other information sources such as those highlighted in the previous section. They also should participate in educational sessions and emergency response exercises designed to help them expand their knowledge and expertise in the area of animal health emergency management.

The Vaccination Unit Leader

The Vaccination Unit Leader is responsible for assisting the Incident Commander(s) and the Operations Section Chief in planning and conducting a successful vaccination program. The goal of such a program is to prevent the transmission of pathogens to neighboring premises. Summarized below are the Unit Leader's general responsibilities as well as his/her responsibilities as related to information gathering, personnel education, and administration.

General Responsibilities—The Vaccination Unit Leader should be identified well before a disease outbreak or other animal health emergency occurs. This individual:

- Ensures that complete, up-to-date contact information is maintained on personnel who are willing and qualified to serve as Vaccination Unit Managers and Vaccination Team Members. Contact information for all vaccination personnel (and alternate personnel, should key staff be unavailable or unreachable) should

include names; postal, express mail, and e-mail addresses; cell, office, and home telephone numbers; and fax numbers. (Also see "Essential External Contacts," below.)

- Assigns Vaccination Unit Members to Vaccination Teams and appoints a Vaccination Unit Manager to supervise each team.

- Assigns Vaccination Teams to various areas or groups of premises.

- Supervises the entire vaccination program and ensures that vaccination schedules are met.

- Serves as a technical resource for information on current vaccination methods and procedures and maintains files of resource materials on these topics.

- Supervises and is responsible for field vaccine evaluation activities.

- Establishes and maintains the local vaccine distribution center(s).

- Organizes, coordinates, monitors, and supervises vaccine storage, security, administration, distribution, and reporting activities.

- Establishes, maintains, and determines personnel needs, making recommendations to the Operations Section Chief**,** as appropriate.

- Assists in developing training as needed for employees under his or her supervision.

- Accounts for vaccine used, based on receipt and processing of reports of vaccine distributed, used, returned, or destroyed.

- Determines the number and types of personnel, vehicles, and equipment needed to conduct vaccination operations and communicates with the Operations Section Chief to ensure that the required resources are available.

- Identifies personnel training requirements and is responsible for (a) ensuring that employees are oriented (by the Safety Officer) to on-the-job hazards and ways to avoid them, (b) explaining Vaccination Team Members' duties to them and training them in vaccination policies and procedures, and (c) ensuring that personnel implement proper biosecurity measures in their work.

- Coordinates vaccination activities with the activities of personnel from other units (e.g., biosecurity, appraisal, euthanasia, and disposal).

- Prepares briefings and reports for the Operations Section Chief on a regular basis and notifies him or her immediately of any problems.

- Verifies the accuracy and completeness of all required reports and submits them promptly for entry into the APHIS Emergency Management Response System or an agreed-upon alternative reporting system.

- Cooperates as appropriate with other emergency response organizations (.e.g., State emergency management agencies).

The Vaccination Unit Leader's responsibilities also include information gathering, personnel education, and administration as summarized below.

Information Gathering—To support the Operations Section Chief effectively, the Vaccination Unit Leader must have updated lists of essential external contacts and access to current, high-quality information in a number of areas associated with vaccination decisions, as highlighted in the following discussion.

***Essential External Contacts*—**The Vaccination Unit Leader must have a current list of the names of important external contact persons along with their postal, express mail, and e-mail addresses; office and home telephone and cell phone numbers; and fax numbers. The list should include complete contact information for the following

- Key AERO staff in adjacent States as well as in one's own State.

- The North American Foot and Mouth Disease Vaccine Bank.

- The U.S. Department of Agriculture (USDA) Veterinary Services (VS) Vaccination Liaison on APHIS' Emergency Programs staff.

- The State Department of Agriculture's Boards of Health and Animal Health in the one's own State and in adjacent States.

- The State Emergency Operations Center (EMOC) and the EMOCs of adjacent States.

- Pertinent manufacturers, distributors, and other sources of equipment and assistance (e.g., companies providing veterinary supplies and equipment for animal handling, vaccination, and vaccine handling and storage).

***Deciding Whether to Vaccinate*—**Although the final decision on whether to vaccinate is made by USDA and APHIS personnel**,** the Vaccination Unit Leader plays a major role in collecting the information on which this decision is based.

Key decisionmakers should use the Decision Tree for the Use of FMD Vaccine (Appendix II) in deciding whether to vaccinate animals for FMD. The Vaccination Unit Leader is responsible for helping to gather all data necessary for effective use of the Decision Tree.

As information is gathered, it may be presented orally and/or in a frequently updated report. The report is to be given only to the Incident Commander and Operations Section Chief as it may contain sensitive information that is not meant for general distribution. In addition to relevant legislation, decisionmakers may wish to refer to a cost-benefit analysis and/or an analysis of whether a successful vaccination and eradication effort can be completed according to alternative scenarios involving various vaccination techniques.

***Vaccine Suitability*—**Decisions as to the antigen strain to be used for vaccine will be made by USDA and APHIS personnel in consultation with the North American Foot and Mouth Disease Vaccine Bank.

Although they have little input into these decisions, Vaccination Unit Leaders and Managers have an essential role to play in owner and public education about vaccination. Accordingly, it is important that these personnel have a basic understanding of the complex interactions of homologous or heterologous strains and serotypes as well as the limitations of the particular vaccine strain administered—both in and of itself and in relation to various species. Heterologous serotype vaccination, for example, may require more frequent "booster" vaccinations to obtain a desired immune response than does homologous serotype vaccination.

Personnel Education—Personnel education is important for many reasons, including the fact that many personnel will, in turn, be responsible for educating premises owners and members of the general public. The Training Unit Leader is responsible for educating a number of personnel, including those discussed below.

***Supervisory Veterinarians*—**Supervisory veterinarians the Vaccination Unit Leader, and the members of the Vaccination Scheduling Group all are encouraged to study these guidelines **and other resources** to optimize their preparedness for assisting with an effective FMD vaccination program.

As part of general preparedness, the Vaccination Unit Leader also should prepare a document providing standard operational procedures (SOP) directives for issues likely to emerge during an FMD outbreak. He or she should then distribute this document to the supervisory veterinarians, who in turn should distribute it to their staffs. The SOP directives should be updated periodically.

***Vaccination Center Personnel*—**Vaccination Center personnel should study Section 3 ("The Vaccination Center") as well as material from State protocols and/or other sources on document reproduction and routing, record filing, and secretarial and telephone-answering procedures. Staff members responsible for procuring, storing, distributing, and accounting for supplies should study material on vaccine procurement; vaccine inventory control and accountability methods; transportation packing; and maintenance of a vaccine's cold temperature through cold chain management.

Personnel responsible for maintaining the cleaning and disinfection area of the Vaccination Center(s) should be thoroughly familiar with the information contained in the NAHEMS "Biosecurity" and "Cleaning and Disinfection" guidelines (in progress). They also should study material on supply inventory control, waste disposal, applicable State pollution laws, and disinfectant application, including Federal/State Environmental Protection Agency regulations affecting the application of disinfectants to equipment and premises. Cleaning and disinfection personnel should be well versed in the use of safety gear (e.g., hard hats, vision and hearing protection, and protective clothing).

***Vaccination Team Managers*—**Vaccination Team Managers should with the Biosecurity Section to create signs or placards briefly explaining on- and off-premises biosecurity protocol for vaccinated premises posting as appropriate. The Vaccination Team Managers also should study material on Vaccination Center establishment and on vaccination reporting and documentation procedures.

If time and resources permit, the Vaccination Team Managers, along with members of their Vaccination Teams if possible**,** should attend an orientation session conducted by training personnel (e.g., on biosecurity and cold chain documentation). The Team Managers also should be provided with additional on-site training and experience.

***The "Buddy" System*—**In the event of a major FMD incursion, many additional Vaccination Centers may need to be organized over time. To accommodate personnel training needs, the Vaccination Unit Leader should select key people from properly functioning groups to train new groups.

Before a key person leaves, however, he or she should serve as a "buddy" in training his or her successor so that a functional, well-trained working group remains. The Vaccination Unit Leader should make every effort to correct any problems before key personnel are transferred.

***Communicating With Owners*—**Owners of vaccinated and nonvaccinated livestock should be kept informed on current developments through a variety of communications media, including factsheets, press releases, paper and/or e-mail newsletters, a Web page, and/or other means.

***Gathering Statistics*—**The Vaccination Unit Leader should gather, document, and regularly update information on animal populations within the potential Vaccination Zone. This information can be obtained from a number of different sources (e.g., AERO Sections, Center for Epidemiology and Animal Health**,** State Veterinarians' offices, the Farm Service Agency, and other State or Federal agencies). Lists of premises on which animals are kept can be validated by local veterinary practitioners. Such lists should be considered confidential.

***Maintaining Requirement Checklists*—**The Vaccination Unit Leader should create and maintain regularly updated lists of personnel, equipment, and vaccine requirements to be used in implementing an FMD vaccination program.

Defining Potential Vaccination Zones—See Section 4, "The Vaccine."

Designating Personnel—The Vaccination Unit Leader should coordinate the designation of required personnel with the AERO Logistics Section. The availability of both APHIS and non-APHIS personnel should be monitored.

Accredited veterinarians for potential AERO employment can be identified using lists obtained from APHIS' National Veterinary Accreditation Program and/or VS Area Offices. Similarly, lists of State employment agencies can be used to identify personnel to assist with animal handling.

Needs for vaccination personnel, vehicles, and equipment will be determined at the time of the animal health emergency by the Vaccination Unit Leader in consultation with Vaccination Team Managers. The Vaccination Unit Leader will work with State emergency management agencies to identify euthanasia personnel with the required expertise from multiple Government and private sources.

The Vaccination Unit Leader should advise the Operations Section Chief of any personnel requirements that cannot be satisfied locally so that arrangements for additional personnel can be made. The Vaccination Unit Leader also will work with appropriate officials to issue contracts and leases regarding any equipment, supplies, or personnel for euthanasia operations.

***Maintaining Owner*—**For information on maintaining contact with owners of vaccinated livestock**,** see Section 6, "Vaccination Procedures."

Liaising With Incident Command --The Vaccination Unit Leader is responsible for designating personnel who will collect information on newly vaccinated premises from the Vaccination Centers and pass it along to the Incident Command office and to other units as appropriate.

Vaccination reports and premises reports, described later in this section, are excellent sources of data. The Vaccination Unit Manager can modify questions from the premises report form to help gather specific information needed by various units.

If a Vaccination Unit Leader receives reports of newly discovered clinical infection from field veterinarians, he or she should forward this information immediately to the Diagnosis and Inspection Section and the Epidemiology Unit.

Administrative Duties—Although the Vaccination Unit Leader has many responsibilities, he or she has a variety of local, State, regional, and Federal resources upon which to draw. In a major FMD outbreak, a number of agencies will coordinate assistance at the local, State, regional, and Federal levels as appropriate.

The Vaccination Unit Leader can request personnel, vehicles, supplies, and equipment required locally from the AERO Procurement? Unit.

Some requirements may involve more than one area of operations. In such cases, the Vaccination Unit Leader should send a request summarizing resources needed at each area of operation to the Logistics Section of the interagency Joint Operation Center (JOC).

At the JOC, the combined APHIS/State team will coordinate resource acquisition and distribution. Resource acquisition may include dispatching local assets, engaging the services of contractors, using State assets, or asking the interagency Mobilization Center Management Team for Federal support.

Personnel—The Vaccination Teams, at least initially, will be composed of State and Federal Veterinarians and two Animal Health Technicians. The Vaccination Unit Leader will assign these and additional personnel to individual sites as needed. In situations involving more than one veterinarian, a single veterinarian will be designated as Team Manager. The size of the team may vary according to the size of the job assigned.

Procuring Additional Personnel— For vaccination to be accomplished in a timely manner, having an adequate number of qualified workers will be essential. Thus, **i**f additional personnel are needed, USDA-accredited veterinarians and local workers may be hired. As a condition of employment, all individuals hired must agree to have no contact with FMD-susceptible species for 5 days after their last premises visit. Nonlocal workers may be provided with a per diem payment, depending on circumstances. Mileage for use of a private vehicle for program work will be reimbursed.

Training Personnel—The Vaccination Unit Leader will oversee the development and coordination of several personnel training sessions. Newly hired workers will attend an orientation session providing them with essential information about their new jobs as well as standard terms of employment and disengagement.

In addition, all vaccination personnel will attend a Vaccination Unit orientation session. This session will include a program overview and information on topics such as vaccine biology, animal handling, and biosecurity, vaccination, and administrative procedures.

Vaccination Team Managers—Veterinarians who are likely to be assigned Vaccination Team Manager responsibilities will be required to attend an extra session on topics relevant to this role. This session will address topics such as effective use of the Vaccination Center(s) and pre-visit contacts with owners in addition to technical topics such as specimen collection and dealing with vaccine-caused anaphylaxis.

Organizing Vaccination Unit Communications—The communications flow within the Vaccination Unit may be organized as shown in Figure 1.

The Vaccination Unit Leader oversees Vaccination Unit communications and ensures that incoming information of interest to other units is forwarded to them promptly. The Vaccination Unit Leader's primary contacts will occur with the Vaccination Unit's Scheduling Group. Although the Scheduling Group schedules approximate dates and times for Vaccination Team visits to a premises, the Team Manager is responsible for contacting the owner to arrange final details—including day, time, and place.

The Scheduling Group—The Scheduling Group is responsible for the approximate scheduling of the Vaccination Team's premises visits, including both vaccination activities and post-vaccination visits with owners. Issues identified by the Scheduling Group may require prompt, direct guidance from the Vaccination Unit Leader. Although the Scheduling Group schedules approximate dates and times for Vaccination Team visits to a premises, the appropriate Vaccination Team Manager is responsible for contacting the owner to arrange final details as to time and place for visits.

The Scheduling Group interacts mainly with owners and with Vaccination Center supervisors**.** The Group's work area will be set up in or near the AERO Communications Center.

The Vaccination Center(s)—The Vaccination Center(s) may or may not be located near the AERO Incident Command Post. The Vaccination Unit Leader will supervise the work of the Vaccination Center(s). Other Vaccination Center personnel will interact primarily with the Vaccination Center Supervisor. The Supervisor serves as liaison between the AERO Incident Command Post and the Vaccination Center personnel and Vaccination Teams.

During a vaccination campaign, a "communications crush" can be expected, primarily in relation to owners' requests for assistance and support from the Vaccination Teams. *It is important that the Vaccination Center Supervisor and the Vaccination Unit Leader hire sufficient staff and set up enough communications equipment to handle these requests.*

Vaccination Team Managers will keep the Animal Health Technicians informed of assignments and ongoing developments and will arrange pre-vaccination visits with owners to confirm equipment, supply, and personnel needs. Team Managers also may use the Vaccination Center, at least to some extent, to help owners find answers to questions they may have after their herds have been vaccinated.

On the pre-vaccination visit, each Vaccination Team Manager will provide the owner with a letter or card with contact information for the Vaccination Center's Scheduling Group and directing the owner to contact the Scheduling Group to schedule herd vaccination. Information on contacting the Incident Command Post and/or State AERO also will be included. The letter or card should contain the names, titles, and office telephone, cell phone, and fax numbers of key personnel as well as their e-mail and regular-mail addresses. Direct communication between owners and the Scheduling Group should be encouraged in order to minimize Vaccination Team involvement with time-consuming scheduling and other details.

The Vaccination Center will be decommissioned after the vaccination campaign, and the Vaccination Unit Leader will reassign communications responsibilities to the Communications Unit. (For additional information, see Chapter 3, "The Vaccination Center.")

***Maintenance of Vaccine Inventory*—**The Vaccination Unit Leader is responsible for vaccine distribution and for maintenance of a running inventory of vaccine supplies. The Vaccination Center Supervisor is responsible for generating reports for the Vaccination Unit Leader detailing vaccine distribution, use, and returned or destroyed supplies.

Reporting

Daily Reporting—The Vaccination Unit Leader should see that the reports identified below are submitted to the Operations Section Chief on a daily basis.

***Vaccine Inventory Report*—**A daily running vaccine inventory should include the total amount of vaccine on hand as well as the number of various-sized vials in the inventory.

***Report on Work Completed*—**This report should include maps of all Vaccination Zones and the locations of all (a) premises with herds to be vaccinated, (b) premises with herds that have been vaccinated, and (c) high-risk premises within the Vaccination Zone.

The report also should contain a simple table showing the number of Vaccination Teams deployed; the total number of animals vaccinated, by species, during the previous day; and cumulative data for each Vaccination Zone, including the number and percentage of premises with herds in need of vaccination.

***Report on Vaccination Personnel Field Performance*—**The Vaccination Unit Leader will track the Vaccination Team's general performance with an eye toward both affirming achievements and identifying potential problem areas. Data will be gathered on matters such as the number of animals vaccinated per day, broken needle reports, accident reports, reports of lost equipment, and public complaints.

***Basic Premises Information Sheets*—**An information sheet (paper copy) will be kept for each premises located within a Vaccination Zone. This document will include:

- The referral control (premises identification) number assigned by Incident Command Post personnel.

- Name of premises owner or manager and contact information (e.g., telephone, cell phone, and fax numbers, e-mail address, postal address, or physical address if different from postal address).

- Farm name, if applicable.

- Postal or physical address at which animals are located

- County, township section, and quarter section in which the premises is located

- The livestocks' Global Positioning System (GPS) location.

- Name and quantity of susceptible species present on the premises.

- Space for noting assignments, completed work, and the name of the Vaccination Team's contact person.

Additional Reports—The data below also will be kept on file for use as needed.

***Vaccination Team Assignments*—**Records of individual vaccination team assignments should be made and kept on file by the Scheduling Group. Assignment delivery completion will be confirmed by the Vaccination Center Supervisor.

***Administrative Cost Reports*—**An up-to-date table of estimated vaccination-area expenditures should be available for use in responding to requests by the Finance Section Chief.

***Vaccine Performance Data*—**At the direction of the Operations Section Chief and the Vaccination Unit Leader, serologic studies of varying extent and duration will be made. These studies involve comparisons of random sera samples, drawn at vaccination, with post-vaccination sera drawn during herd revisits.

***Vaccine Storage and Security*—**The Vaccination Unit Leader should report on vaccine storage and security as needed. For further information, see Chapter 4, "The Vaccine.")

Vaccination Schedule—The Vaccination Unit Leader is responsible for preparing reports in connection with his or her responsibility to establish, supervise, and coordinate the vaccination program and for ensuring that vaccination schedules are met.

The Vaccination Team Manager

Typically, the Vaccination Team Manager is given responsibility for a clearly delineated area or a specific number of premises. The Vaccination Team Manager supervises the

activities of the Vaccination Unit Members and assigns them, usually in teams, to infected or contact premises.

The Vaccination Team Manager:

- Provides assistance and support to the Vaccination Unit Leader.
- Orients Vaccination Team Members to their duties, providing them with training in vaccination policies and procedures.
- Assigns tasks (e.g., coordination of vaccination activities) to Vaccination Team Members and other vaccination personnel and supervises this work.
- Assists the Vaccination Unit Leader in determining the personnel, vehicles, and equipment required to implement a vaccination program efficiently.
- Prepares regular briefings and reports for the Vaccination Unit Leader and notifies him or her immediately of any problems or issues.

The Vaccination Unit Member

The work of the Vaccination Unit Member on an infected or contact premises is essential to the containment and control of a disease outbreak. Each Vaccination Unit Manager may be responsible for a designated area or a certain number of premises.

Before the Vaccination Team's arrival on a premises, a foreign animal disease diagnostician (FADD) or other designated official will have visited the premises to observe the animals and take samples. Evidence obtained by the FADD and/or other investigators, which will be documented in the EMRS or other authorized reporting system, will indicate that the animals and materials are at risk of transmitting an FAD pathogen and that a vaccination program must be initiated and maintained. Upon arrival on the premises, the Vaccination Unit Member should assist the Vaccination Unit Manager in the Unit Manager's tasks as outlined earlier in this section.

Hazard Communication—Before any vaccination work is initiated, the Vaccination Team Members should be briefed fully by Training Unit personnel (see the NAHEMS "Roles and Responsibilities" Guidelines, in progress) as to the nature of the disease with which they are dealing. Vaccination Team Members, in turn, will brief the owner, the owner's family, and premises employees on hazard avoidance, especially if the hazards involve a zoonotic disease. Vaccination Team Members will coordinate their activities closely with teams from other units (e.g., the Appraisal, Biosecurity, Euthanasia, or Disposal Teams) that may visit the premises. (These units will have been briefed previously on hazard avoidance.)

Specific safety precautions or hygiene requirements should be explained before the team enters the premises. This is particularly important if a zoonotic disease is involved.

Respirators should be supplied if the personnel are at risk from a disease organism or chemical hazard, if significant amounts of dust are generated, or upon individual request. (For further information on respirators, see the APHIS Respirator Program Guidelines in APHIS' "Safety and Health Manual," Chapter 11, Section 3.)

Personnel Orientation Factsheets

Certain sections of this document may be especially relevant to the responsibilities of individual vaccination personnel. Accordingly, the Vaccination Unit Leader may wish to distribute one- or two-page laminated factsheets on various responsibilities or tasks to these individuals. For a sample factsheet, see "Biosecurity Dos and DON'Ts" (Appendix I).

Assessing Needs

Needs for vaccination personnel, vehicles, and equipment will be determined at the time of the disease outbreak by the Vaccination Unit Leader in consultation with Vaccination Unit Managers. The Vaccination Unit Leader will work with State emergency management agencies to identify Vaccination Team Members with required expertise from multiple Government and private sources.

The Vaccination Unit Leader should advise the Operations Section Chief of any personnel requirements that cannot be satisfied locally so that arrangements for additional personnel can be made. The Vaccination Unit Leader also will work with appropriate officials to issue contracts and leases regarding equipment or personnel for the vaccination program.

3 The Vaccination Center

The Vaccination Center serves as the central operations facility for all of the field operations of the Vaccination Unit. With respect to vaccination, the Center serves three primary, interrelated functions:

- Communications/assignments**.**
- Provision of supplies
- Cleaning and disinfection of vaccination teams and equipment suggestion?

Each of these functions involves a separate area of responsibility. The functions may or may not be fulfilled on the same premises.

Special attention must be given to ensuring that clean supplies going out into the field are not contaminated by items coming back from the field. This requirement usually best can be met by demarcation of a "Clean Area" and "Dirty Area" for facilities, equipment, supplies, and personnel.

Although Vaccination Teams may find it necessary to make daily visits to multiple premises, the utmost care should be taken to avoid spreading infection between premises. Iatrogenic (inadvertent medical) spread of the FMD virus could undermine the entire vaccination program. VS personnel should identify, suggest, and document corrective procedures taken to reduce the chance of premises-to-premises pathogen transmission.

Personnel

The Vaccination Center Supervisor or his/her assistant—A Foreign Animal Disease Diagnostician (FADD) should be in charge of the Vaccination Center. This individual will designate three people to be responsible for the communications/assignments**,** supply, and cleaning and disinfection functions, respectively.

The Vaccination Center should be staffed and operational 24 hrs per day, **7** days per week during the vaccination campaign. Upon completion of the campaign, a minimal number of staff members will be assigned to handle communications and administrative matters. Eventually, as the disease event subsides over time, the Vaccination Unit Leader and Operations Section Chief will reassign all activities to other AERO units.

Functions

As noted earlier, the work of the Vaccination Center focuses on communications/assignments**,** supplies, and cleaning and disinfection—each of which is discussed briefly below.

***Communications*—**The communications staff will:

- Schedule Vaccination Teams' premises visits.
- Facilitate communication between the Vaccination Unit Leader, the Vaccination Teams, the owners, suppliers, and other interested parties,
- Provides information to the Information Unit to prepare factsheets, posters, newspaper articles, and information for television news stories, news releases, and the Internet on the vaccination program.
- Serve as a message center for Vaccination Teams and for owners needing information on vaccination.
- Provide Vaccination Teams with access to telephones, mail, fax, and e-mail delivery and support services.
- Collect reports, perform data entry services, and maintain computer and paper-copy files for the Vaccination Unit.

Supplies—The supply staff at the Vaccination Center will:

- Clean and distribute coveralls, appropriate footwear, and protective gear appropriate to the season.
- Maintain vaccination supplies and ensure that adequate quantities of supplies are available.
- Distribute vaccine to the Vaccination Teams and will establish and maintain bookkeeping systems with which to document incoming and distributed vaccine.
- Arrange with the Vaccination Section to obtain vaccine at least once daily from the central storage unit. When ambient temperatures are high, it may be necessary to arrange deliveries twice daily and to keep the vaccine in insulated containers with ice gel-packs.

***Cleaning and Disinfection*—**The Vaccination Center staff will:

- Collect and process materials to be incinerated.
- Collect, clean, sterilize, and repackage reusable equipment in a timely manner.
- Process (sterilize, disinfect, and/or dispose of) clothing, footwear, and safety equipment returned by the Vaccination Teams.

- Disinfect returned, unopened vaccine vials; document cold-chain management; record the vials' serial numbers in inventory records; and maintain cold-chain storage until the vaccine is used or discarded.

- Obtain, maintain, and monitor shower facilities and supplies for personnel disinfection.

- Steam clean large animal handling equipment.

Vaccination Team Members are responsible for:

- Cleaning and disinfecting supplies and equipment)

- Taking their vehicles through an automated car wash prior to returning to the Vaccine Center.

- Emptying and vacuuming their vehicles at the Vaccination Center.

- Restocking vehicle with disposable supplies.

Vehicles, animal handling equipment, and reusable vaccination supplies will be used on one premises only for a given day. If these items are removed from a given premises, they must be cleaned, disinfected and/or sterilized completely before they are returned to that site or to any other site.

Vaccination Center Site

A number of factors need to be considered in choosing the site for the Vaccination Center. Local emergency coordinators can be helpful in identifying and evaluating suitable locations.

Location—Ideally, the Vaccination Center will be located centrally within the Vaccination Zone. Two or more Vaccination Centers may be necessary if the Zone and number of Vaccination Teams is large, if natural physical boundaries inhibit ease of mobility, or if multiple sites are identified. The Vaccination Unit Leader and Operations Section Chief will make the final decisions as to the location of the Vaccination Center site(s).

Facilities—In choosing a Vaccination Center site, the use of currently existing facilities (e.g., armories, Veterans Administration hospitals, school gymnasiums, and empty slaughter plants) is preferred. On-site shower and toilet facilities may be available, or portable facilities may be need to be ordered and delivered by the Logistics Section. (See the discussion of Administration in Section 2, "The Vaccination Unit Leader's Responsibilities")

An important consideration in site evaluation is the availability of water and of waste-water handling facilities. Preferably, waste water should be directed to a municipal waste-handling facility.

Storage—Preferably, the Vaccination Center site will have ample room for indoor and outdoor storage. The storage areas should be secure or should be capable of being made secure.

Utilities—Potential Vaccination Center sites should be evaluated for power line capacity and adequacy of electrical distribution (e.g., for multiple computers). In addition, multiple telephone lines will be needed for computer modems. If automobiles and large equipment are to be cleaned and disinfected at the Vaccination Center, the adequacy of outdoor drainage also should be considered.

Equipment

Equipment ordered for use at the Vaccination Center (e.g., autoclaves, washing machines, and dryers) should be purchased as self-contained units (to maintain maximum portability). Such equipment can be purchased or leased in large sizes if needed.

If large equipment is purchased, portability should be kept in mind as the Vaccination Center may be moved to new vaccination areas over time. Some large equipment (e.g., portable corrals, chutes, gates, and trailers) will be kept at the Vaccination Center and assigned as needed.

Refrigeration—Refrigeration equipment in which to store at least a 1-day vaccine supply should be maintained at the Vaccination Center. Basic monitoring equipment will be used to document proper refrigeration.

Equipment Cleaning and Disinfection—Careful cleaning and disinfection of equipment is essential to avoid spreading FMD between premises. The Vaccination Team is responsible for the cleaning and disinfection of the equipment they have been issued.

***Large Equipment*—**The Vaccination Team will clean and disinfect the equipment on the vaccination premises and put it in clean plastic garbage bags. At the Vaccination Center, staff will steam or pressure spray and re-disinfect the equipment before further use. Vaccination Center staff should assess both the cleanliness and the physical condition of the equipment before reissuing it. As mentioned, equipment should be used on only one vaccination premises per day.

***Smaller Equipment*—**Smaller equipment (e.g., automatic syringes, ropes, and hog holders) that has had direct contact with animals should be sterilized rather than disinfected before reuse.

***Vehicles*—**Vaccination Center staff will designate a special area at the Center for the cleaning and disinfection of vehicles with interiors that are potentially contaminated with

the FMD virus. Center staff will provide Vaccination Team members with equipment (e.g., vacuum cleaners and upholstery shampoo) for use in vehicle cleaning and disinfection.

***Personal Safety Equipment*—**The Vaccination Center will store and distribute personal safety equipment. Almost all of this equipment will be disposable.

First aid kits, to be issued by the Center, will be kept in Vaccination Team vehicles and will be used on a site only if needed. Should the kits be used, they will be disposed of by incineration.

Clothing

The Vaccination Team will place reusable clothing such as coveralls, footgear, stockings, and rubber suits and in plastic garbage bags for cleaning and disinfection and the Vaccination Center. Vaccination Center staff will wash and autoclave reusable clothing and footgear before reissuing it.

Disposal

To prevent inadvertent pathogen transmission, special care should be taken to dispose of non-reusable supplies, equipment and any biomedical waste (sharps containers) safely.

Incineration—A list of licensed medical incinerators should be obtained from the State regulatory agency and agreements made for the scheduled disposal of combustible trash and other materials. Examples of such materials include disposable clothing, unused vaccine vials, disposable syringes, and paper and plastic waste materials.

Land Fill—Certain waste materials (e.g., solid metal or wood waste) are best disposed of in a land fill. A local waste disposal company should be hired to pick up and haul away such materials.

Sharps Biomedical Waste—The Vaccination Team should carry a new small- or medium-sized sharps container along on each new assignment. The outside of the container will be disinfected before leaving the premises. Containers will be disposed of in a manner consistent with State and local laws.

4 The Vaccine

If a vaccination campaign is implemented, the Vaccination Unit Leader must be able to access vaccine promptly, use it effectively, and store it safely. This chapter provides an overview of plans and issues in these areas.

Ordering Vaccine

FMD vaccine is available from the North American Foot and Mouth Disease Vaccine Bank. For details on procedures for vaccine ordering and shipment, see Appendix III, "Protocol for the North American Foot and Mouth Disease Vaccine Bank Vaccination Program."

Designating the Vaccination Area

Upon confirmation of an disease outbreak, the AERO Incident Commander(s) will establish a Quarantine Zone for surveillance, control, and eradication of the disease. The Quarantine Zone or area will consist of two parts: the High-Risk Zone and the Buffer Zone. Designation of High-Risk and Buffer Zones reflects many considerations, including the extent of the known infection, natural barriers, and readily recognizable landmarks such as rivers, roads, and major highways.

Establishing the Vaccination Zone—Typically, the Vaccination Zone is considered as covering the same area as the Quarantine Zone. Once the Vaccination Zone has been determined, all premises within it should be identified, including premises with borders extending outside the zone. If a premises is partially within the zone, the entire premises must be considered to be within the zone.

Ring Vaccination—"Ring vaccination" refers to the inoculation of animals on the periphery (or ring) of a Vaccination Zone, starting from the periphery of the Buffer Zone and working inward, as detailed below.

High-Risk Zone—The first available Vaccination Teams will vaccinate animals on contiguous premises around the infected premises and on other high-risk premises. All swine operations within the High-Risk Zone and the Buffer Zone are to be considered high-risk herds. In most cases, teams that vaccinate high-risk herds will be limited to single premises visits for any given day. However, this may be affected by available personnel and number and size of herds to be vaccinated.

After all high-risk herds have been vaccinated, the teams will vaccinate the herds on the periphery of the zone. After all of the herds on the periphery of the zone are vaccinated, the teams will then work inward from the periphery toward the center.

Teams working at the periphery will be working with herds that are either of unknown status or clinically negative for FMD. The teams vaccinating these herds will be allowed to move through the Vaccination Center's Cleaning and Disinfection process and return to the premises to vaccinate another low-risk herd on the same day. The overall goal is to vaccinate all herds within the ring area in the shortest possible time (ideally, one week or less).

Ring Size—Classically, the distance of ring vaccination has involved a 2.5- (per Piehl, instead of 2-) to 15-mile radius around the infected zone. The actual ring size will vary according to factors such as the predominant species in the area, population density, and environmental factors, including prevalent wind direction, and other natural and human-made barriers. The final decision as to ring size will be made by the Vaccination Unit Leader in consultation with the Operations Section Chief and the Incident Commander(s) and will require their approval.

Depopulation—After a decision to depopulate within a Vaccination Ring has been made, teams will start with the peripheral herds and work inward. Vaccination is to be utilized as a means of controlling spread of infection until the at-risk animals can be euthanized.

Quarantines—Owners of vaccinated herds will be issued a State quarantine. Movement within the Vaccination Ring will be accomplished under shipping permits, according to quarantine procedures. Movements out of the ring only will be permitted directly to approved slaughter plants, again under shipping permits and seals. Approved slaughter plants cannot export meat products and must meet the Office International des Epizooties' Standard 2.1.1.15. For further information on quarantines, see the NAHEMS "Quarantine and Movement Control" guidelines, in progress.

Indemnity—Procedures for compensating owners for the loss of their animals and property (e.g., contaminated forage) will be coordinated with AERO's Appraisal Unit. For further information, see the NAHEMS "Appraisal and Compensation" guidelines, in progress.

Refusal to Allow Vaccination—Owners who refuse to allow their animals to be vaccinated will be reported to the Operations Section Chief, who will determine appropriate action in consultation with the AERO Incident Commander(s) and State and/or USDA legal advisors.

The premises of owners who refuse to allow vaccination must be noted clearly on the Vaccination Unit Leader's maps and lists indicating the status of herds within the Vaccination Zone. (For further information, see Chapter 6, "Vaccination Procedures.")

Follow-up Vaccination—The ultimate goal of a vaccination program is to use all appropriate "stamping out" procedures simultaneously to eradicate the epidemic as quickly and efficiently as possible. In making decisions about follow-up vaccination, factors such as herd depopulation and use of newborns as sentinels must be considered.

Ring Depopulation—If the epidemic is controlled within 6 months, the Vaccination Ring will be depopulated in the same manner as described above (e.g., starting at the periphery and working toward the center).

Herd Newborns—The Incident Commander(s) will address the issue of whether newborn herd additions in previously vaccinated herds need to be vaccinated. If the area spread is prevalent, newborns should be vaccinated at the appropriate age. If the epidemic is under control, the newborns may be left as sentinels indicating the presence of low-grade infection that may be present in vaccinated herds.

(Editor's note: Move this paragraph up under Follow-up Vaccination.)
If the epidemic is not controlled within 6 months and the capacity or funding for depopulation is not present, a decision to provide booster vaccinations to vaccinated animals will need to be made at the Incident Command level or higher.

Disposition of Vaccinated Animals and Associated Products—During an FMD epidemic, decisions will have to be made concerning the disposition of vaccinated animals and products derived from them. Pressure is likely from a number of different interests on this matter.

FMD-infected vaccinated animals can harbor the virus sub-clinically, and it is possible that products from these animals can lead to further transmission of the virus. Accordingly, it is possible that human or animal use of vaccinated animals will not be permitted.

Decisions on the disposition of vaccinated animals and animal products within the Vaccination Ring will be made by USDA Emergency Programs staff in consultation with individual States. The States are the primary source of laws restricting the movement of such materials.

Vaccinated animals will be held on their premises by State quarantines. The movement of such animals within a Vaccination Zone will occur by permit only. Animal movement within a Vaccination Zone may be allowed under permit after thorough documentation of the area's immune status and of the risk associated with such movement.

Movement of animals outside the Vaccination Zone will occur by special permit only The sole exception to this rule involves movement, under permit, directly to a slaughter plant.

USDA Emergency Programs staff currently is working on protocols for processing animal products to eliminate the FMD virus. Until these protocols are in place, Appendix IV, the "European Union Document on FMD Control and Eradication from the Official Journal of the European Communities, March 31, 2001" will be the reference guide

Time Frame for Completion—Although an emergency ring-vaccination program ideally should be completed within 1 week, many factors may influence this goal. Such factors

include size of the job; personnel availability and placement; availability of resources, including financial support; vaccine availability and distribution; and owner cooperation.

The Veterinary Officer is encouraged to set appropriate goals and to work toward them regardless of obstacles. Often, getting the personnel and supplies in the right area at the right time is the biggest challenge.

In the event of multiple vaccination rings spread over a large area, staggered or delayed completion times may be necessary. In consultation with the AERO Operations Section Chief, the Vaccination Unit Leader should prioritize vaccination goals, trying to complete a ring within those goals and then reassigning resources to other areas or portions of the Incident Command Post. High risk herds should be prioritized to maximize use of vaccine.

Barrier Vaccination—Barrier vaccination involves use of a natural or human-made barrier, such as a river or a State boundary line, as the starting point for demarcating the Vaccination Zone. In barrier vaccination, the Vaccination Zone does not necessarily encircle the FMD-infected area.

High-Risk Herd Vaccination— High-risk vaccination focuses on the inoculation of high-risk animal groups such as:

- Herds that include animals purchased from infected herds.
- Herds that have had contact with an infected herd, either (a) directly or (b) indirectly through fomites.
- Swine herds that have had contact with an infected herd or are located in either the High-Risk or Buffer Zones.

Preferably, high-risk herds will be covered by preemptive slaughter regulations. In the absence of such regulations, vaccination—if approved—will proceed as quickly as possible. Vaccination teams are not to visit other premises on the same day that they have visited a high-risk premises.

Blanket or Wide-Area Vaccination—A vaccination program carried out over a wide area typically would occur under a Federal and/or State order.

As the area of vaccination enlarges, security within and surrounding the area tends to be more difficult to maintain. Movement within the Vaccination Zone will remain by permit only.

Permanent, unalterable identification of vaccinated animals is required. Examples include tattoos, an ear notch, an ear-hole punch, or an injectable micro-chip.

Strategic Vaccination—Strategic vaccination is a vaccination approach that is utilized under constrained circumstances (e.g., limited resources or fast-moving disease spread).

Under such a scenario, the Incident Commander(s) might wish to vaccinate a specific animal population while simultaneously devoting most of the available resources to other areas in order to contain an infection.

The ultimate goal of strategic vaccination is to "take (disease) fuel away from the fire," especially in cases in which the number of new FMD cases is growing faster than they can be handled or in which depopulation and disposal teams are having difficulty keeping up with their workloads. Strategic vaccination can be used to help reduce the population of susceptible animals so that AERO teams will have time to "catch up" with the infection and contain it.

Under such a scenario, an AERO Vaccination Team—typically composed of a veterinarian and two technicians—may be reduced to a single technician. For further information on the technician's duties, see the discussion of strategic vaccination in Chapter 5.

Vaccine Response

The development of a reasonable degree of animal immunity to FMD can be expected 7-8 days after vaccination. In cases in which vaccinated animals are exposed to a field virus before vaccinal immunity is developed, the clinical manifestations of the disease may be marginal to indistinct, and the epidemiology of the disease may be subject to variation. For this reason, no movement other than to slaughter will be permitted for 14 days after vaccination.

If the animals are to be slaughtered for human consumption, withdrawal time must be considered. Lesions in vaccinated animals might be difficult to detect and might go unobserved unless extreme care is taken during clinical inspection. Masked infection may go unrecognized by livestock owners and thus may not be reported. In such cases, unvaccinated young stock can serve as completely susceptible controls (sentinels?).

Vaccine Storage

FMD vaccine must be held within specified temperature parameters at all times and must be stored in a unit with special features as outlined below.

Receiving From the Vendor—When the vaccine has arrived at the local airport, the condition and the temperature-monitoring devices should be checked and documented. The vaccine should be moved to refrigerated trucks and taken to the designated vaccine central storage area.

Central Storage Requirements—The temperature throughout the vaccine central storage unit should be kept at as even a level as possible. Temperature sensors should be used to ensure that all the vaccine is kept within specified temperature limits. The volume of space necessary to contain the vaccine is shown in Table 1.

Table 1. Vaccine Shipping Dates, Doses, and Required Storage Space

	Total Doses	Total Storage Volume
Shipped on day 3	xxxx	xxx ft3
Shipped on day 7	xxxx	xxx ft3
Shipped on day 14	xxxx	xxx ft3
Shipped on day 21	xxxx	xxx ft3
Total:		

Note: This is confidential information, not to be disseminated openly.

In addition to the space requirements listed here, space needs to be allotted for air circulation above, under, and to the sides of the vaccine, along with space enabling people and handcarts to move. The shipments may need to be divided and stored in several smaller coolers. Temperature within the space will be documented electronically or on a chart recorder, and the data will be filed for future reference.

Refrigeration—The vaccine must remain in a cold-chain status at 37 º- 46 ºF (3 º-8 ºC) throughout the storage period and until such time as the vaccine is injected into an animal.

Protection From Sunlight—Vials of vaccine must be protected from direct sunlight.

Central Storage Alarms—Alarms should be set to sound if the temperature within the space moves outside a 37-46 º F (3 **º** C-8**º** C) range or in the event of a compressor failure. An (automatic?) alarm dialer should notify at least two telephone contacts. In all cases in which the alarm is sounded, the Vaccination Unit Leader should be notified, and his or her assessment of the situation should be documented and submitted to the AERO Operations Section Chief.

Protection From Equipment or Power Failure—Alternative storage space or back-up compressor or condenser systems must be ready for use in the event of equipment failure. An emergency source of electrical power also must be available in case the power supply fails.

Adequate Construction—The vaccine central storage unit must be constructed with disinfectable surfaces and with floors able to withstand handcart and foot traffic.

Work Area—The vaccine central storage unit must include sufficient space for administrative inventory control. The unit should be well lighted, with a lights "on/off" indicator at the access door.

Telephone—A telephone and list of important telephone numbers, including those of VS and maintenance personnel, should be placed inside the vaccine storage unit.

First In, First Out—Vaccine supplies are to be dispensed on a "first in, first out" basis.

Partially Used Vials—Vials of vaccine are considered usable for 36 hours after opening, if properly refrigerated. Partially used vaccine vials should be destroyed after the premises visit. (Editor's note: The preceding information appears to be at variance with the package insert, which says to "Use entire contents when first opened. Dispose of … used vaccine in accordance with directions from the National regulatory authorities")

Vaccine Security

Access—The area surrounding the vaccine storage unit should be secured. If the Incident Commander(s) believes the security of the central storage unit is threatened, the services of armed military or private guards should be utilized.

Access to the unit should be restricted to a select group of personnel approved by the Vaccination Unit Leader, the Incident Commander(s), and the Operations Section Chief. For purposes of vaccine accessibility, one person must be within a readily accessible distance of the vaccine storage unit 24 hours per day, 7 days per week.

The locks on the door of the unit should be reliable and securely attached. The keys to the locks should be of a type that is not readily reproducible.

Vaccine Refrigeration Options

Several vaccine refrigeration options may be considered, including those described below.

Local Facilities—Use of local refrigeration space, if available, usually is the least expensive option. Examples include the facilities of (1) public institutions such as schools, universities, and veterans' hospitals and (2) private refrigerator or freezer rental companies, including vacated slaughter or locker plants.

FMD vaccine storage will not be permitted in refrigeration space simultaneously used for food storage. Likewise, refrigerators containing products held at extreme temperatures will be unsuitable.

A positive aspect of using the refrigeration facilities of private rental companies is that such companies are likely to be insured, bonded, and at least somewhat secure. A potential issue with the use of whole-building (explain?) refrigerators is that areas within the space may be colder or warmer than the required 2 º-7ºC

Customized Space—If resources permit, space customized to vaccine storage requirements can be built. Under this option, for example, a storage area built to the Vaccination Unit Leader's specifications could be refrigerated with ammonia systems provided by a private company.

Such a space can offer features such as temperature evenness, properly sized doors, and reliable security, including alarms and off-site monitoring. The expertise of the company's plant managers can be used in monitoring and maintaining the refrigeration equipment, relieving veterinarians of the need to learn these skills.

This type of space provides potential emergency on-site backup refrigeration space. It also may provide on-site freezers that can be used to freeze hundreds of gel-packs for field use simultaneously.

Mobile Trucks—Two types of mobile truck system currently are in common use.

Plate System—The most common and least expensive system involves two plates in which a chemical solution is entrapped. The plates are located in the floor and walls of the storage space, frozen, and/or charged overnight, and then removed from the energy supply, cooling the storage space during the day. Unfortunately, temperatures in this type of system can vary by as much as 15 º F or more, making the unit unsuitable for vaccine storage.

Forced-Air System—A second type of truck system involves a forced-air unit with two sources of power (diesel and electric) and a compressor. Microprocessor controllers are used to maintain the temperatures of the unit within proper vaccine storage specifications. The units are manufactured in sizes ranging from 1-1/2- to 2 tons (for a truck body) to full reefer size (suitable for a semi).

Full-Size Reefer Units—A potential problem with full-size refrigeration (reefer) units is maintenance of uniform temperature over the full length of the unit in view of the fact that the compressor/condenser is located at the front end. In this situation, the vaccine should be stored on pallets that allow for air circulation, and a central air tube should be used to help maintain airflow and temperature uniformity throughout the unit.

Although the reefer's walls may be insulated, temperatures can rise fairly quickly if the truck's compressor/condenser fails. Thus, reefers are not the best choice for long-term on-site storage.

Smaller Forced-Air Units—Smaller forced-air units are preferable to full-size reefer units in delivering vaccine from central storage to the vaccination team in the field. Such units tend to maintain temperature more effectively than full-size units and tend to be much less expensive.

Custom Refrigeration—Local retailers may sell a variety of custom refrigeration units, ranging from a small display refrigerator to a large walk-in refrigerator/freezer unit sized according to client's specifications. The walk-in units are prefabricated and assembled on site, and the company may offer ongoing assistance with service and maintenance. Possible options include temperature recorders, alarms, dialers, status sensors, and remote inquiry systems.

The lead time required for ordering a custom on-site unit typically is about 3 to 4 weeks. Although the cost may be high, the client has the advantages of owning the unit. One advantage is portability: The unit can be disassembled, moved, and set up again within a few days.

Although stationary refrigeration-unit technology can be used in an insulated reefer unit, the compressors would not run while the truck is traveling. Back-up power for these units can be obtained from generators.

Accountability

Vaccine accountability includes procedures involving vaccine shipment receipt, distribution of vaccine to vaccination teams, maintenance of vaccine security, and vaccine recycling.

Initial Inventory—Once ordered, the FMD vaccine will be shipped from the North American Foot and Mouth Disease Vaccine Bank to a location designated by the Vaccination Unit Leader. The Bank will pay the shipping costs, subsequently invoicing APHIS for reimbursement.

The Bank representative and the contractor (authorized AERO receiving official) will verify the completeness of the vaccine shipment by comparing it with the order. The receiving official will document receipt of the vaccine and will provide the Bank representative with written acknowledgment of receipt.

VS officials will then take possession of the vaccine, verifying the number of boxes and vials and ensuring that the emulsion is intact. They also will examine temperature indicator strips accompanying the shipment to ensure that cold chain management has been maintained.

Vaccine Issuance to Vaccination Teams—A person designated by the Vaccination Unit Leader will consign the vaccine from the central storage facility directly to the Vaccination Center. Before issuance, the vaccine vials must be stamped with the date of receipt and marked.

The amount of vaccine issued daily to the Vaccination Team will be based on the estimated number of animals to be vaccinated plus 25 percent, and then rounded up to the next complete vial.

The vaccine vials need not be stamped with the date upon reissue. The Vaccination Unit Leader must provide the AERO Operations Section Chief with a summary of vaccine use on the appropriate form. This summary must be based on the vaccinator's daily record of vaccinations as documented on the form.

An ongoing vaccine inventory will be compared to the projected population of animals to be vaccinated so that potential shortfalls in vaccine supply can be foreseen and so that adequate vaccine supplies can be ordered in a timely manner.

Vaccine Recycling

Vaccination teams will do everything in their power to use the vaccine issued to them wisely. Unfortunately, miscalculations or miscounting can lead to nonuse of issued vaccine. Unopened vaccine that has been kept refrigerated and has not been taken onto a high-risk premises can be "recycled" by returning it to the Vaccination Center.

Vaccination teams returning unopened vials to the Vaccination Center will document that the vaccine was maintained under cold-chain conditions while under their control. The Vaccination Center will document vial serial numbers and will disinfect the vials, store them properly, and reissue them to a Vaccination Team the next day along with documentation of cold-chain maintenance. The vaccine will not be returned to the vaccine central storage unit. All unopened vials taken onto high-risk premises will be destroyed.

Destroying Partially Used Vaccine Vials—Vaccine vials that have been removed from the transporting vehicle, brought onto a premises, and partially used will be destroyed.

Disposal of Empty Vaccine Vials—Empty vaccine vials will be either (1) burned on site or (2) returned to the Vaccination Center, where they will be disinfected, placed in a plastic garbage bag, and discarded.

Investigating Vaccine Stored Outside Recommended Temperature—If the temperature of the central storage unit moves outside recommended limits, the effectiveness of all affected vaccine should be considered compromised. An investigation will be initiated and a report submitted to the Vaccination Unit Leader as soon as possible. The report will address the following:

- What caused the temperature of the storage area to move outside the recommended limits?

- How long was the vaccine stored outside the recommended temperature limits, and at what temperature(s) was it stored?

- How much (i.e., all or part?) of the stored vaccine was stored outside the recommended temperature limits?

- What recommendations can be made to help prevent future incidents of this nature?

5 The Vaccination Team

A Vaccination Team typically consists of a veterinarian, who serves as the Vaccination Team Manager, and one or more Animal Health Technicians. If more than one veterinarian is present on a single premises, one veterinarian will be designated as Team Manager.

Team Responsibilities

The Vaccination Team Manager is responsible for on-premises discussions with the owner liaison between the owner and Vaccination Unit. The Team Manager also is responsible for reporting any information that may help the Incident Commander(s) delineate the epidemiological features of the outbreak.

Government veterinarians or accredited non-Government veterinarians) will administer vaccine to designated animals. Technicians should be permitted to administer vaccine only under the direct supervision of a veterinarian.

In general, the Animal Health Technicians will assist the Team Manager with vaccine procedures and with equipment and animal handling. Preferably, one technician will assist the veterinarian directly. An additional technician will keep supplies available and will have primary responsibility for maintaining the biosecurity line established near the Vaccination Team's vehicle.

Briefing Government Personnel

The Vaccination Unit Leader will provide all workers, including Federal and State personnel, with a complete briefing upon their arrival at the Vaccination Center. The briefing should include basic information about FMD as well as about proper methods of inoculation, biological actions of FMD vaccine, biosecurity measures, and administrative matters such as housing, pay, and rotation schedules.

Assigning Work

The Vaccination Unit Leader will set up a system for notifying personnel of their work assignments. It is the Vaccination Team Manager's responsibility to inform the members of his or her team of the details of their assignments.

Hiring Local Personnel—The Finance Section will ensure that full-time, part-time, and temporary personnel are supplied with full information about their terms of appointment, including fees, allowances, and reimbursable expenses. Identification cards must be issued to all employees and recovered upon termination of their assignments. These duties will be coordinated with the administrative staff of the Finance Section.

Assistance From On-Site Employees—It is of strongly recommended that the employees on a premises be used to present animals for vaccination. The Finance Section will reimburse the premises owner directly for these services.

If the owner is unable to supply the workers or equipment needed to present the animals for vaccination, the Vaccination Team Manager will use the services of Government employees as well as Government equipment as necessary. Tasks associated with this responsibility will be coordinated with the administrative staff of the AERO Finance Section.

Obtaining Equipment

The Vaccination Team is responsible for handling both disposable and reusable equipment in such a manner as to prevent the spread of the FMD virus. Disposable equipment should be burned on the premises or disinfected, put into plastic garbage bags, and returned to the Vaccination Center for incineration. Reusable equipment should be disinfected, put into plastic garbage bags, and returned to the Vaccination Center for further processing.

Animal Handling Equipment—Ideally, automobiles and trucks used for the vaccination program should be able to transport or tow such as animal chutes, trailers, and portable gates. The Finance Section is responsible for procuring the types and number of vehicles and the types of equipment needed by the Vaccination Unit. Vehicles and equipment should be maintained so that they are safe to use, in good working order, and readily disinfectable.

Vaccination Teams are responsible for following strict biosecurity procedures concerning the vehicles they use. As such, they should be familiar with vehicular biosecurity procedures outlined in the NAHEMS "Biosecurity" guidelines (in progress).

Vehicle Equipment—Each vehicle should have communications equipment such as a Government or private cell phone, Government VHF/UFH radio, or similar device. Each vehicle also should contain a first aid kit, car-accident reporting kit, diagnostic sampling kit, and small tool kit.

Animal handling equipment and vehicles should be pressure washed before resuse. Exceptions to this policy may be made only at the direction of the Vaccination Unit Leader or the Operations Section Chief.

Equipment for Biosecurity—To support biosecurity practices, the Vaccination Team should bring the following equipment with them on each premises visit:

- A small container of liquid soap and enough approved disinfectant to clean and disinfect contaminated or potentially contaminated personnel and equipment before leaving the premises.

- A brush, pail, and hand-pump sprayer for use in applying disinfectant.
- Cleaning equipment, including a small utility shovel, a foot scraper, and a length of garden hose.
- Disposable latex or plastic gloves.
- A supply of small hand towels and/or paper towels.
- A pair of rubber or above PVC overalls and jacket for each team member.
- Washable boots or disposable boots.
- Cloth coveralls for each team member (for use when leaving the premises) or Tyvek® coveralls for movement on and off the premises.
- Cloth tennis shoes.
- A supply of large plastic garbage bags.

Occupational Safety Equipment—The Vaccination Team should bring equipment for use in promoting occupational and workplace safety, including

- Hard hat helmet
- Ear plugs
- Disposable respirators

Vaccination Equipment—As mentioned earlier, the Vaccination Team should bring an anaphylaxis kit to each premises with them for use in case an animal goes into anaphylactic shock after being vaccinated. Additional vaccination equipment is discussed below.

Needles—The team leader is responsible for ensuring that the following is brought to each premises:

- Needles of the proper quantity and size to complete the day's vaccinations.
- A sharps container for used needles.

Owner groups may appreciate being consulted about the types of needles used. Newer needles may have enhanced flexibility and/or may include ferrous material to facilitate metal detection at slaughtering plants.

Syringes—The Vaccination Team Leader is responsible for bringing the following equipment for each premises visited:

- Two 50 cc syringes for vaccine handling.
- Three 5 cc disposable syringes.
- Four multidose syringes. (These syringes should be of good quality, easily disassembled, and sterilizable, with readily available replacement parts.)

Coolers and Thermometers—To maintain cold-chain conditions for the vaccine, the team should bring:

- A sturdy, commercial-grade Styrofoam™ cooler or a metal or plastic cooler with good thermal properties.
- A dial thermometer, encapsulated refrigerator thermometer, or single-use digital temperature recorder.

Miscellaneous Items—The Vaccination Team should also bring:

- A notepad (preferably waterproof).
- Pencils
- Forms with which to fill out a vaccination report, a premises report, and a vaccine inventory list.

Strategic Vaccination

As mentioned in Chapter 4, strategic vaccination is used in cases in which a vaccination program is implemented using limited resources (e.g., a reduced labor supply). As mentioned, such a situation might occur if a specific population of animals needs to be vaccinated while most available resources simultaneously are being devoted to FMD containment in other areas.

In strategic vaccination, an AERO Vaccination Team—typically composed of a Vaccination Team Manager (a veterinarian) and one or more Animal Health Technicians—could be reduced to a single technician. This technician would be responsible for:

- Documentation of the maintenance of cold-chain conditions for the vaccine.
- Explaining the vaccination process to the owner.

- Provision of limited clinical diagnostic screening.

- Documentation of animal identification, types of animals vaccinated, and compliance with animal-movement restrictions.

Although some people advocate giving FMD vaccine to the owner for unrestricted use without supervision, this should be done only as a last resort. A policy of unrestricted use may encourage trading partners and the domestic livestock industry to conclude erroneously that the FMD situation is endemic and uncontrollable.

Unrestricted vaccine use also may contribute to a situation in which unused vaccine surfaces in an illegal market situation, well outside the restricted movement areas. To avoid the possibility of producer fraud or vaccine misuse, at least one Vaccination Team member—either a veterinarian or a technician—should accompany the vaccine to the premises and document its proper use.

In strategic vaccination, as in other types of vaccination, basic program components such establishment of a Vaccination Center, orientation of personnel, and standard vaccine storage and distribution procedures should be initiated and maintained. Additional concerns, summarized below, include biosecurity, animal identification, determination of a vaccination pattern, and administration of booster doses.

Biosecurity—The technician engaging in strategic vaccination must make every effort to follow field cleaning and disinfection procedures, including use of the cleaning and disinfection area of the Vaccination Center, before proceeding to another premises. It is strongly recommended that personnel visit only one premises per day.

Procedural changes allowing personnel to make same-day visits to multiple premises need to be approved by the AERO Incident Commander(s), Operations Section Chief, and Vaccination Unit Leader. Procedures need to be established to assure observers that Vaccination Teams are not spreading disease from one premises to another.

***Use of Agricultural Workers*—**The use of agricultural workers, preferably those experienced in handling livestock, must be documented not only for financial reasons but also for biosecurity reasons. Such documentation must include a record of workers' movement between premises.

Agricultural labor reimbursement is meant for owners with access to workers who usually work solely for the owner and who can help with vaccination tasks—rather than for freelance agricultural workers who move around an area. If a roving labor force of agricultural workers is used to help with vaccination, the workers should be hired directly by the AERO as contractors. This will help ensure that they follow proper cleaning and disinfection procedures between premises visits.

The Vaccination Team is responsible for ensuring that agricultural workers thoroughly clean and disinfect all vaccination and animal restraint equipment used. In

discussions with each owner, the Vaccination Unit Leader must emphasize and affirm the ongoing importance of restricted herd movement and herd biosecurity.

Animal Identification—Preferably, individual animal tags (large or small metal tags) and/or an ear notch or ear punch will be used to identify animals. However, the Vaccination Unit Leader can decide to eliminate identification under certain circumstances.

The decision to require no identification is linked directly to Vaccination Area security. Every effort should be made to contain vaccinated animals within a specified area.

The need for identification probably will lessen in the future as marker vaccines are developed. Such vaccines will permit the serological differentiation of vaccinated animals from animals with field infection. Accordingly, owners may place a higher value on the verifiable disposition of a group of vaccinated animals than on the identification of individual animals.

In addition to strategic vaccination, standard vaccination techniques are available. These techniques are described in Chapter 4.

Checking on Vaccine Availability—The current FMD vaccine requires a booster 4-5 weeks after initial vaccination. The Vaccination Unit Leader should check on the availability of vaccine supplies with the North American Foot and Mouth Disease Vaccine Bank. Any vaccination program that does not follow the manufacturer's recommended protocol needs to be approved by the APHIS Administrator and supported by scientific evidence appropriate to the particular situation.

6 Vaccination Procedures

The Vaccination Team's vaccination activities begin with a previsit contact with the owner and extend through the processes of vaccination handling and administration.

Pre-visit Contact

After a Vaccination Team has been assigned to a premises, the Vaccination Team Manager will contact the owner by telephone or e-mail. (In the event of an FMD outbreak, time will be too short for postal communications to be useful.) In this conversation, all of the owner's questions and concerns should be discussed thoroughly.

The Team Manager and owner also should discuss the health status of the animals on the premises. If the animals are believed to be healthy, an appointment should be made for them to be vaccinated. If, however, the owner believes the livestock have FMD clinical signs, the appointment will be delayed and the Vaccination Unit Leader notified so that a diagnostic team can visit the premises to determine the health status of the animals.

Before the Vaccination Team arrives, the owner should arrange for a complete census of the animals on the premises.

Biosecurity

As mentioned earlier, observance of strict biosecurity measures is paramount in preventing the spread of FMD between premises. All team members should be familiar with the biosecurity protocols outlined in the NAHEMS "Biosecurity" guidelines (in progress).

A "clean line" will be established and clearly marked between the place where the Vaccination Team's vehicle is parked (an area believed to be free of FMD and therefore clean) and the premises (which will be presumed not to be clean). All standard cleaning and disinfection procedures must be observed before personnel and/or equipment move from the premises across the clean line.

The Vaccination Team—After a Vaccination Team has visited a premises, team members will clean and disinfect all equipment, footwear, and clothing thoroughly. As soon as these items have been brought across the "clean" line to the vehicle, the items will be secured in a plastic garbage bag. The team will wear coveralls and boots while driving back to the Vaccination Center.

Vehicles—Vehicles will be parked in an area considered clean. Any vehicle crossing the clean line into the premises area will be subject to standard disinfection techniques.

Before the vehicle leaves the premises, a Vaccination Team member will spray its tires thoroughly with disinfectant. The vehicle—as well as any potentially contaminated large equipment—will be taken through an automated car-wash facility before it is returned to the Vaccination Center.

Equipment—Disposable articles of equipment will be disinfected and sealed in a plastic garbage bag. The outside of the bag also will be disinfected. Some disposable articles may be incinerated using on-premises facilities.

Reusable articles will be cleaned, disinfected, and placed in a plastic garbage bag, the exterior of which then will be disinfected. Large equipment will be cleaned near the premises buildings and disinfected before they are brought across the clean line.

Breaking Biosecurity in Emergencies—If a medical emergency arises and standard cleaning and disinfection procedures are not followed, a team member should notify the Vaccination Center of the actions taken as well as the ultimate destination of the contaminated vehicle.

The Vaccination Team should follow standard biosecurity techniques outlined elsewhere in this manual as well as in this discussion.

Vaccine Handling

The proper handling of vaccine is essential to maintaining its potency and thus to the success of an FMD vaccination program.

Cold-Chain Conditions—It is important that cold-chain conditions be maintained from the time the vaccine is received until it is administered to the animal. The vaccine may be exposed to ambient (surrounding) environmental temperatures for no more than 30 minutes prior to administration.

If a cooler accident occurs and the vaccine temperature moves outside of the 37 º- 46º F (3-8 ºC) range required for storage, the Team Manager will contact the Vaccination Center for recommendations or will arrange for delivery of fresh vaccine.

The Team Manager is responsible for ensuring that the cold chain conditions have been maintained until the time of administration. He or she will certify this in writing.

Mixing and Dispensing—For AFTOPOR, the objective is to administer the dose of vaccine by the deep intramuscular route to a cervical site. This objective will be assisted greatly by the proper restraint of the animals to be vaccinated. *It is important to make advance arrangements for the availability of sufficient assistance so that the vaccinator can focus on administering the vaccine properly.*

Vaccination Teams should work in a quiet, methodical manner. Only the amount of vaccine necessary for the immediate task should be removed from the cooler for use. This should not exceed the amount necessary for 30 minutes' work.

The vaccine within each vial should be made homogeneous by mixing it *gently* before the needles are inserted into the vial. To mix the vaccine, rotate the vial, base over apex, for no fewer than 20 revolutions by hand.

Do not mix the vaccine by vigorous shaking because this leads to the entrapment of air bubbles in the vaccine. Once air bubbles are present in the vaccine, the vaccinator will find it impossible to measure the correct dosage volume of vaccine. In addition, air bubbles can cause excessive side-effects at the animal's injection site as well as long-term pathology in the animal.

It is important to ensure that the air-bleed and vaccine withdrawal needles are inserted correctly. (See Figure 2.)

When it is time to inject the vaccine:

- Mix the vaccine carefully in the vial, using the method described above.
- Insert the vaccine withdrawal needle through the center of the vial plug.
- Insert the air-bleed needle to its full length—off-center through the vial plug.
- Invert the vial.
- Connect the sterile syringe to the vaccine withdrawal needle.
- Withdraw the vaccine dose required.
- Connect the syringe to the injection needle.
- Make a deep intramuscular injection.

Vaccine Administration

Vaccine administration covers a wide range of considerations, including vaccine dosage, injection technique, animal identification, diagnostic surveillance, post-vaccination premises biosecurity, reporting of adverse reactions, contact with the owner, dealing with owners who refuse to permit vaccination, assessment of general herd health status, and handling difficult animals. Each of these considerations is discussed below.

Dosage—The standard dosage of FMD vaccine is 2 cc per animal, administered via a deep intramuscular injection.

Revaccination—The North American Foot and Mouth Disease Vaccine Bank's recommendations concerning animal age and revaccination are listed in Table 2 and Table 3, below.

Injection Technique—A preferred injection site is in the muscles of the neck in front of the shoulder The position of the injection should be at a point in the side of the neck about one-third of the distance below the top ridge of the neck and two-thirds above the lower edge of the neck. This position will ensure avoidance of the great vessels in the lower neck.

Try to insert the needle at a 45-degree angle to the skin surface rather than at a 90-degree angle to avoid leak-back of the vaccine. If blood-borne parasites or diseases are suspected or known to be present in the region, considerably stricter measures must be taken to avoid allowing the vaccination needle to pick up and disseminate the virus.

***Needle Type and Reuse Issues*—**The recommended" type of needle to be used for various types of animal is as follows:

- Large ruminant: 16-18 gauge (G) x 1-1/2 inches.
- Small ruminant: 19-21G x 1-1/2 inches.
- Large swine: 18G x 1-1/2 inches
- Small swine: 20-21G x 1 inch

If a needle is kept clean, it can be reused for about 10 to 20 vaccinations. It then should be discarded safely.

Broken Needles—Every effort should be made to restrain animals to prevent needles from breaking off and to retrieve needles that do break off. If the needle cannot be retrieved, a note documenting the incident should be included with the premises vaccination report.

The animal carrying the needle should be identified in such a way that it can be singled out easily at a distance. The documentation will be used to identify the animal so that if and when it goes to slaughter, the affected area can be located and trimmed.

***Anaphylaxis*—**If an animal goes into anaphylactic shock after vaccination, epinephrine should be administered. Vaccination Teams should bring an anaphylaxis kit with them each time they visit a premises for purposes of vaccination. The kit should be sealed and able to withstand standard disinfection procedures.

Restraint—The Vaccination Team Manager is responsible for seeing that proper human and animal restraint is used. Objectives in the use of restraint include the following:

- No humans are injured.
- No animals are injured.
- No property damage occurs.
- The vaccine is administered properly and efficiently.

Animal Identification

Animals can be identified in several ways, as described below.

Ruminants—A colored metal ear tag is the only acceptable form of primary official identification for ruminants of all sizes. If area security or owner adherence to movement restrictions is in question, an optional permanent identification method (below) can be used as well. Each animal should be double tagged according to a numbering system and in a color that is unique to the herd being identified in the area.

***Metal Ear Tags*—**Large and medium-size metal ear tags, available in assorted colors, shapes, and sizes, should be made available by The Vaccination Officer in pink or another approved color and used according to a designated numbering scheme.

Floppy Ear Tags—An alternative to the metal tag is the floppy tag, which is made of re flexible material and is available in assorted colors, shapes, and sizes. In the future, manufacturers may incorporate radio frequency identification devices (RFID) into floppy tags. Such devices have features that could be useful in an identification program.

Optional Identification—The use of optional identification must be approved on a case-by-case basis by the Vaccination Unit Leader and the Operations Section Chief and must be documented properly by the Team Manager. Permanent optional identification methods include:

- A tattoo portraying a unique character in green paste ink.
- An ear notch pattern.
- An ear punch.

An injectable RFID also may be used, though this method (is temporary?). For additional information on animal identification in FMD situations, see Appendix VI, the "Trilateral FMD Animal Identification Working Group Report of August 22-23, 2000."

Swine—In general, all swine on a premises must be identified as part of an FMD vaccination program. The only exception to this rule occurs in cases in which a verified "all in-all out" management system is being used. In this system, a building is (1)

emptied of livestock, (2) cleaned and disinfected, (3) restocked with animals from the same source within 1-2 weeks; (4) emptied and cleaned and disinfected again after 1-2 weeks; and (5) restocked with animals from the same source. No other animals enter the building during the time between stocking and emptying.

Metal Ear Tags—Small and medium-size metal ear tags, available in assorted colors, shapes, and sizes, should be made available the Vaccination Unit Leader in pink or another approved color and used according to an approved numbering scheme. Each animal should be double tagged.

Paint—Swine may be marked for identification by painting a number on their backs.

Optional Identification—Alternative swine identification methods, both of which are permanent, include the ear notch pattern and the ear punch as well as other methods discussed under optional identification for ruminants.

Diagnostic Surveillance

In an FMD situation, diagnostic surveillance methods utilize both serology studies and clinical inspection.

Serology—Prior to vaccination, the Vaccination Teams will draw blood samples from 10-15 head of randomly selected cattle. These animals will be identified clearly so that post-vaccination blood samples can be drawn to help assess vaccine potency. All blood samples should be labeled clearly and refrigerated

Clinical Inspection—Before vaccination is begun, the Vaccination Team must conduct a clinical inspection of all stock on a premises—including animals ineligible for vaccination—for signs of FMD. On large premises, it may be practical to inspect and vaccinate the animals in distinct, clearly defined groups.

If a team member detects signs or suspected signs of FMD, he or she must suspend operations and report immediately to the Vaccination Team Manager. In consultation with the Vaccination Center, the Team Manager will arrange for a foreign animal disease diagnostician to visit the premises, inspect the animals, perform standard diagnostic procedures, and report the results to the Vaccination Center.

The Vaccination Team should not attempt to make a diagnosis and should avoid any further handling of the animals in order to limit exposure to the virus. If an animal suspected of having FMD is discovered while working with the herd—and the animal already is restrained—diagnostic samples should be taken, the animal identified clearly, and the vaccination procedure stopped.

Vaccination Teams that encounter infected premises should not be given vaccination assignments for 48 hours or for a period of time suitable to the AERO Incident Commander(s) and Operations Section Chief. The Vaccination Unit Leader will adjust

vaccination assignments accordingly. Team members considered contaminated could be reassigned to the Vaccination Centers or other appropriate areas.

Post-vaccination Biosecurity

The Vaccination Team Manager will provide the owner with a factsheet on post-vaccination premises biosecurity procedures and will discuss it with him or her, emphasizing the importance of strict compliance. The factsheet should include the following topics:

- The biological action of the FMD vaccine in the owner's herd (e.g., initiation and length of immunity and common misconceptions about vaccination).
- Ways to inspect a herd or flock for clinical FMD signs as well as ways to report signs or suspected signs immediately.
- Basic aspects of official quarantines (e.g., animal movement restrictions, procedures for moving animals properly, and requirements for quarantine lifting).
- Slaughter-withdrawal times associated with vaccination (e.g., to help owners determine when meat is safe for consumption).
- The difference between vaccination and biosecurity and the fact that vaccination should not be considered a substitute for biosecurity measures. Related topics include restrictions on human access to the premises, potential FMD introduction via on-premises animal movement or contact, and risks associated with the sharing of agricultural equipment.
- The importance of limiting human access (e.g., visits by artificial insemination personnel) to premises in the vaccination area until at least 14 days have elapsed from the date of vaccination of all eligible, susceptible animals on the premises.
- Essential points of the indemnity program to be used (if applicable).
- Animal loss, reporting of loss, and carcass disposition.
- Options for ultimate herd disposition (e.g., typical alternatives such as depopulation.

Reporting Adverse Reactions

The Vaccination Team should encourage the owner to identify and report animals exhibiting vaccination reactions so that the Vaccination Team can examine them on a future visit to the premises. VS personnel will document the incidence of vaccine

reactions and their potential causes. Suitable treatment may be administered on a case-by-case basis, as appropriate.

Contact Information

The Vaccination Unit Leader will provide the owner with the following contact information:

- A 24-hour-per day, toll-free telephone number
- A fax machine number
- An Internet mail address
- A postal address

The owner should be encouraged to contact the Vaccination Center to report any newly ill or deceased animals and to reschedule previously scheduled premises inspections as necessary.

Post-vaccination Inspection

Post-vaccination inspection of livestock for low-grade FMD infection will be necessary at regular intervals. The Vaccination Unit Leader should request that the Diagnosis and Inspection Unit to handle these inspections to according to the following guidelines:

- High-risk herds: Daily inspection for 14 days after the last known potential FMD contact, with inspections at 3- to 4-day intervals thereafter.
- Within 2 miles of an infected premises: Inspection at 3- to 4-day intervals for 2 weeks following vaccination and at 5- to 7-day intervals thereafter.
- Peripheral areas: Inspection at 5- to 7-day intervals.

Herds will be sent to slaughter beginning at the outside of the Vaccination Zone. VS personnel will examine all vaccinated and sentinel stock prior to issuing a shipping permit allowing for off-premises movement.

If the disease epidemic prevails and movement restrictions are relaxed within a Vaccination Zone, animals should be inspected prior to permitting movement from the zone. Vaccine boosters also may be administered as appropriate.

Refusal to Vaccinate

For any number of reasons, livestock owners may refuse a request for vaccination. The Vaccination Unit Leader or an individual designated by the Vaccination Unit Leader is responsible for handling these refusals on a case-by-case basis, as efficiently as possible.

Some owners' refusals may be based on misinformation, philosophical positions, or lack of proper physical or human resources. Owners' individual situations should be documented along with potential solutions to which the owner might agree.

The Vaccination Unit Leader will report the names of owners refusing vaccination to the AERO Operations Section Chief, who will determine the appropriate next steps in consultation with the Incident Commander(s) and Legal Advisor. The Vaccination Unit Leader must indicate the premises of such owners on the map showing the Vaccination Zone and on the list indicating the status of herds within the Zone.

In some cases, addressing the owner's concerns may resolve the situation. If agreement cannot be reached, the owner should be referred to State compliance authorities for action and/or professional counseling. If the herd or flock is at high risk and the owner cannot be persuaded to vaccinate, State or local law enforcement officials may need to isolate him so that a Vaccination Team can visit the premises to perform the necessary vaccinations.

Genetically Irreplaceable Livestock—An owner may be reluctant to permit vaccination of livestock considered genetically irreplaceable. Such owners can apply to the Vaccination Unit Leader for exemption of their livestock from vaccination. The application should include:

- A biosecurity plan describing methods to be used to protect the livestock from exposure to FMD.

- A surveillance plan—involving both visual inspection and regular drawing of serological samples—to be conducted by trained, accredited veterinarians.

Owners granted an exemption must sign an agreement as to the disposition of the animals if FMD is detected or if the biosecurity and surveillance plans are executed improperly.

Herd Health Assessment

The Vaccination Team should assess each herd's overall health status before vaccination begins. Herds that are malnourished or affected with a common domestic disease potentially affecting its vaccine response should be identified.

If there is any doubt as to the herd's response to vaccine administration, the Vaccination Unit Leader should be consulted about the advisability of skipping vaccination and placing the herd on a depopulation list. Malnutrition—or the producer's inability to maintain proper feeding levels—also would be grounds for moving a herd to immediate depopulation. In either case, the Operations Section Chief will make the decision whether or not vaccination can be skipped.

If depopulation is not an option, vaccination should continue and a subsequent booster followup program conducted and documented. Owners can be referred to State and local producer groups for assistance with feed acquisition.

Any direct, overt violations of animal welfare laws on the part of the owner should be reported to the Vaccination Unit Leader, who will in turn report such violations to the local authorities. Vaccination personnel need to be alert to situations in which they can become the object of an owner's anger and should be prepared to take appropriate action.

Difficult Animals

If the owner and vaccination crew are unable to corral certain livestock, even with additional help and equipment, the matter should be referred to the Disposal or Wildlife Units. Referral should occur in cases in which:

- The owner believes that the animals cannot be corralled.
- The animals have not been captured within a 3-day time period (see below).
- The animals have escaped from the owner's premises and are at large.

The only realistic option for dealing with such animals is long-distance euthanasia, which should be accomplished as soon as possible by trained, authorized personnel. The owner will be indemnified for these animals.

Indemnification—If, as mentioned, animals at large as a result of attempts to corral them for vaccination and are subsequently destroyed by authorized personnel, the owner should receive indemnification. However, if animals are loose for other reasons and/or if the animals are destroyed by neighboring owners, the owners of the animals may or may not receive indemnification, depending on the circumstances.

Time Frame—Vaccination of escaped animals should be completed within 3 days after vaccination of the remainder of the herd. A minimum number of vaccination personnel should be sent to the premises for this second or "recall" visit.

On this visit, vaccination personnel should make a quick visual assessment of the clinical disease status of the entire herd and should note any vaccine reactions. The 3-day time frame can be altered by the Vaccination Unit Leader depending on personnel availability and on the amount of disease risk to the population in question.

Animals at large should be destroyed immediately. The situation calls for immediate action, and no leeway can be given.

7 Maintaining Vaccination Records

The Vaccination Team will keep careful records of all vaccinations. Proper recordkeeping involves the use of VS Form 4-26, "Brucellosis Vaccination Record," as well as adequate data-entry and computer support, and timely processing.

The Vaccination Record

The VS Form 4-26 can be adapted for use in keeping FMD vaccination records.

If the Incident Commander(s) would like to create a new form specifically for FMD, modifications might include:

- Change the title to "Foot-and-Mouth Disease Vaccination Record."
- The form should have two parts to allow for both the original and an owner's copy.
- In the "Kind of Herd" block, replace "Kind of Herd" with "Species"
- Revise Block 1 to read: I have vaccinated, with FMD vaccine, all animals listed hereon and, to the best of my knowledge, the vaccine cold chain was maintained until the time of vaccination.
- Revise Block 3 to read, "The vaccine temperature prior to administration was ____ º F. The type of animal identification used was (tag, tattoo, etc.).

Computer Support

As part of preparedness, an adequate number of personal computers should be available and kept in good working order. A generous supply of paper, printing cartridges, and other office supplies should also be available.

Software—The preferred software for vaccination recordkeeping is the package produced by and available from the Center for Epidemiology and Animal Health (CEAH) in Ft. Collins, Colorado. If this package is unavailable, the Vaccination Unit Leader will direct the Procurement Unit to purchase a micro-based database package and to develop a simple vaccination application.

Data Entry—If CEAH-based software is used, data-entry personnel trained in its use may be available from USDA or from local State agriculture departments. If such personnel are unavailable, data-entry personnel will need on-site training with the chosen database application.

***Data Entry Fields*—**At minimum, data for the following fields should be entered in the database:

- Owner
- Owner's address
- Owner's telephone number
- GPS coordinates
- Vaccination date
- Vaccination Team number
- Vaccine serial number
- Animal identification (primary and secondary)
- Species
- Age
- Sex
- Breed
- Reason for vaccination
- Total number of animals vaccinated
- Disposition of the animal(s)

Timely Processing

Documents generated by Vaccination Teams will be completed and submitted prior to their cleaning and disinfection in the Vaccination Center.

Documents with an assigned Julian number will be faxed to the data entry personnel. The originals will be held in a dry environment until they can be turned in and filed at the Vaccination Center. The entry of premises data into the database should be completed within 24 hours of the time of vaccination date.

The Vaccination Unit Leader or a designated associate is responsible for the review and verification of the vaccination report and for arranging followup action as appropriate.

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Acronyms

AERO—Animal Emergency Response Organization.

APHIS—Animal and Plant Health Inspection Service (www.aphis.usda.gov). An agency of the U.S. Department of Agriculture.

C&D—Cleaning and disinfection

FAD—Foreign animal disease

FADD—Foreign animal disease diagnostician

NAHEMS—National Animal Health Emergency Management System

TDD—Telecommunications device for the deaf

USDA—United States Department of Agriculture (www.usda.gov)

VS—Veterinary Services. A unit of the Animal and Plant Health Inspection Service.

Glossary

Anaphylaxis—A drug reaction indicating hypersensitivity; also known as anaphylactic shock.

APHIS—The Animal and Plant Health Inspection Service. An agency of the U.S. Department of Agriculture.

Barrier vaccination—Vaccination involving the use of a natural or human-made barrier, such as a river or a State boundary line, as the starting point for demarcating the Vaccination Zone.

Blanket vaccination—A vaccination program carried out over a wide area; typically would occur under a Federal or State order.) Also called wide-area vaccination.

Buffer Zone—Area within a Quarantine Zone that is outside the High-Risk Zone. Designation of a Buffer Zone reflects many considerations, including the extent of the known infection, natural barriers, and readily recognizable landmarks.

Challenge tests—Tests in which the immunity of an animal is "challenged" through introduction of a disease agent.

Cold chain management—Uninterrupted maintenance of vaccine chilling within defined parameters and management.

Depopulation—Termination of animals' lives and the disposal their carcasses for disease control purposes.

Fomite—An inanimate object or material on which disease-producing agents may be conveyed (e.g., feces, bedding, or a harness).

High-risk zone—Area within a Quarantine Zone that is inside the Buffer Zone. Designation of a High-Risk Zone reflects many considerations, including the extent of the known infection, natural barriers, and readily recognizable landmarks.

High-risk vaccination—A vaccination approach that focuses on the inoculation of high-risk animal groups.

Indemnity—Compensation of owners for the loss of their animals.

Index herd—The animal herd within a Quarantine or Vaccination Zone that is infected the first herd in an area to be confirmed with an animal disease.

Owner—The person who owns a group of animals or a premise animals are housed on.)

PD50—The value at which 50 percent of vaccinated animals will resist challenge to their immune systems.

Premises—A defined area or structure that may include part or all of a farm, enterprise, or other private or public land, building, or property.

Pyrexia—A fever, or febrile condition. Can be said to be present if body temperature exceeds the normal range for the particular age and species. (Blood & Studdert)

Quarantine—Legal restrictions imposed on a place, animal vehicle, or other thing, limiting movement.

Quarantine zone—Area established by the for surveillance, control, and eradication of FMD. Consists of a High-Risk Zone and a Buffer Zone.

Sentinel—Typically, an animal used to warn of the presence of disease as part of a surveillance program. If an epidemic is under control, newborn animals may be left unvaccinated so that they can serve as sentinels indicating the presence of any low-grade infection that may be present in vaccinated herds.

Serum, (pl. sera)—The clear portion of any animal or plant fluid that remains after the solid elements have been separated out. (Blood & Studdert)

Stamping-out—Eradication procedures based on the quarantine and slaughter of all infected animals and animals exposed to infection. (FROM AUSTVET DISPOSAL MANUAL.)

Strategic vaccination—A vaccination approach that is utilized under constrained circumstances such as resource limitations (e.g., vaccinating a specific animal population while simultaneously devoting most available resources to other areas in order to contain an infection).

Vaccination zone—Typically, covers the same area as the Quarantine Zone.

Ring vaccination—The inoculation of animal herds, starting on the periphery (or ring) of a Vaccination Zone and working inward toward the center of the ring.

Ring size—In ring vaccination, the diameter of a Vaccination Zone; traditionally involves a 5- to 15-mile radius around the infected zone. The actual ring size will vary according to factors such as predominant species in the area, population density, and environmental factors, including prevalent wind direction, and other natural and human-made barriers.

Wide-area vaccination—A vaccination program carried out over a wide area; typically would occur under a Federal or State order. Also called blanket vaccination.

Appendix I
Sample Personnel
Orientation Factsheet

Biosecurity: DOs and DON'Ts*

Before ENTERING a premises,

DO:

- Park your vehicle away from site production facilities and/or ensure that your vehicle's tires, wheel wells, and undercarriage have been cleaned with soapy water so they are free of dirt and debris and/or that your vehicle has been taken through a pressure car wash.

- Designate a "clean" area in your vehicle—usually the passenger compartment. Keep it separate from the "dirty" area—usually the trunk or cargo area.

- Put on clean coveralls, boots, hat, gloves, and other apparel and use only clean equipment and supplies.

- Wash your hands with soap and water.

- Consult with the owner to identify an arbitrary line on the site demarcating a "clean" side and a "dirty" side.

DON'T:

- Enter a site's or vehicle's "clean" area unless you have disposed of or cleaned and disinfected all clothes, footwear, hats, gloves, equipment, supplies, and other sources of pathogen transmission.

- Attempt to disinfect a surface unless it first has been thoroughly cleaned (i.e., so it is free of visible organic material).

- Drive your vehicle on a premises any more than necessary. An on-site vehicle should be used for on-site transportation whenever possible.

**Note:* Additional biosecurity and cleaning/disinfection procedures are required to address the risks posed by serious zoonotic diseases.

(continued)

Biosecurity: DOs and DON'Ts

(continued)

Before LEAVING a premises,

DO:

- After returning to the vehicle area, use a brush and approved disinfectant to clean and disinfect all reusable clothing and equipment thoroughly—including personal items such as eyewear and jewelry. If these items are harmed by disinfectant, they may be washed thoroughly with soap and water or—if an acid-susceptible virus such as foot-and-mouth disease is involved—dipped in vinegar (acetic acid).

- Clean vehicle exteriors and trailers—including tires, wheel wells, and undercarriages—with soapy water so they are free of dirt and debris and/or take them through a pressure car wash.

- Place disposable coveralls (turned "inside out"), boots, and other soiled items in a plastic garbage bag to be left with the owner or placed in the "dirty" area of your vehicle.

- Dispose of the disinfectant solution according to label instructions.

- Dispose of all plastic garbage bags containing soiled supplies in a manner that prevents exposure to other people or animals.

- Wash your hands with soap and water.

- Clean and/or launder all reusable clothing and equipment.

- At the end of the day, take a shower. Personal hygiene should include shampooing your hair, cleaning under your fingernails, and clearing your respiratory passages by blowing your nose, clearing your throat, expectorating into a sink with running water, and washing your hands with soap and water.

DON'T:

- Bring "dirty" paperwork into the clean area of your vehicle.

- Visit another susceptible site until 12 hrs have passed.*

**Note:* The minimum waiting period of 12 hrs applies only to official animal health emergency personnel who follow biosecurity procedures on their premises visits. For other premises visitors, the minimum waiting period is 5 days.

Appendix II
Decision Tree for the
Use of FMD Vaccine

DECISION TREE/MATRIX

The development of this decision tree and matrix resulted from a request at the Tripartite Exercise 2000 Program. It was determined to use a decision tree flowchart combined with a decision matrices.

The rationale for this choice was that a *decision tree* has linear reasoning and can only evaluate single factors sequentially. Thus, simple linear logic:

I.e. AδBδCδDδFδGδH = decision i.e. VACCINATE cannot be devised

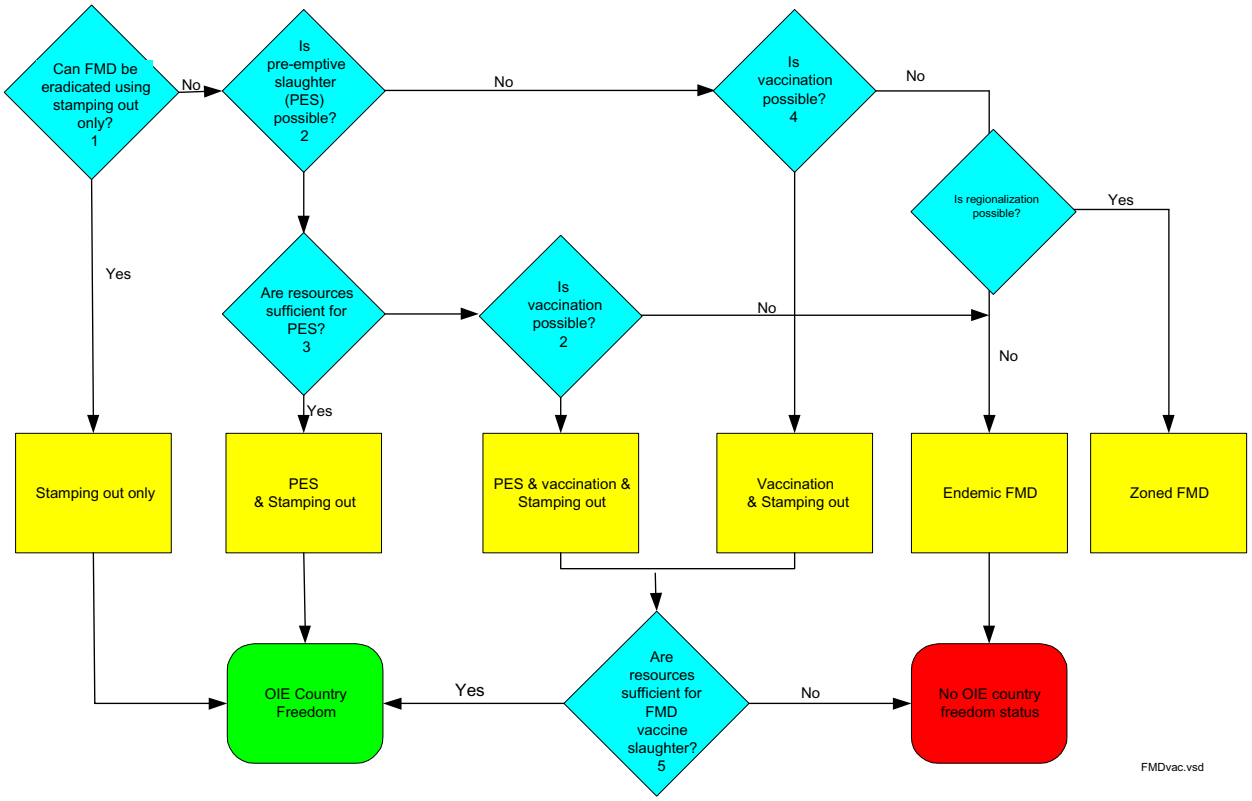
For non-linear or multifactorial decisions, a *decision table* or *matrix* is required with the following logic,

I.e. *If* A + C +F *then* VACCINATE; or *If* A + C +F +H *then* PRE-EMPTIVE SLAUGHTER

A *decision matrix* conceptually evaluates factors in parallel, not in sequence and thus has the capacity to consider multiple factors at the same time. Connector words such as *and*, *even if* and *but* can be used to weight the factors.

However, a decision matrix also does not reflect decision making in reality because human reasoning cannot consider all factors simultaneously. Logical reasoning seeks to group related factors. Thus, a *decision tree* flowchart was developed with five decision boxes. The decision flow chart is illustrated in Figure 1. The decision process starts from the top left (decision box 1) and proceeds to decision box 5 in the bottom right of the figure.

The Decision Tree for FMD Vaccine Use



Each decision box is supported by a *decision matrix* where appropriate factors are listed for consideration. The factors have been grouped into four pivotal factors that characterize the nature of the epidemic (OUTBREAK FACTORS) and four pivotal factors that describe mitigation measures for the outbreak (MITIGATION FACTORS). Each pivotal factor has numerous sub-factors described below.

OUTBREAK FACTORS are:

- Contact Rate
- Host or Species affected/species at risk
- Status of Outbreak
- Environmental

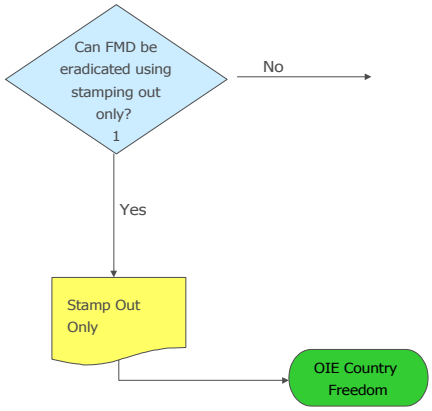
MITIGATION FACTORS include:

- Physical Resources
- Human Resources
- Socio-political factors
- Economic considerations

Note that only factors appropriate to the specific decision box are provided. For example, *decision matrix 1* is the only matrix that contains all the outbreak factors. *Decision matrices 2-5* contain only mitigation factors in addition to stamping out of infected herds. In order to leave the decision box, one must determine the direction by

deciding YES or NO considering all the factors and sub-factors in that box. Tables are available to facilitate record keeping of decisions in Appendix 4.1

Decision Box 1
Can FMD be eradicated using stamping out only?



In this decision box, all outbreak factors and mitigation factors must be considered. This is the point of departure from the preferred, traditional policy of stamping out.

1. **Contact Rate**

Modeling in the USA suggests that is there are fewer than 5 contacts per week stamping out may be sufficient. Contact Rate includes:

1.1 Kind *of Farms* - For example, dairies and feedlots tend to have a higher rate of movements in and out as opposed to other types of operations in particular a back yard producer. So, if the affected area has a lot of dairies and/or feedlots, the weight given to this factor should be increased

Modeling in Australia suggest:

Feedlot - 1000 cattle over 24 hr infected an area of 0.5 km2, 3.4 km downwind
5000 cattle over 24 hr infected an area of 6.2 km^2, 15.2 km downwind
10000 cattle over 24 hr infected an area of 26 km^2, 37.2 km downwind

1.2 *Direct and Indirect Movement* - Is the movement of animals (direct), people or equipment (indirect), or possible vector such as wildlife? The frequency and movement of animals from infected farms is more important than equipment or people.

Indirect movement includes fomites such as equipment, contamination of supply delivery vehicles, veterinarians and farm workers. It also includes marketing of animal products and by- products.

Distance of movements is also important for spread of the outbreak.
Efficacy of movement controls is critical (see Human Resources) but movement here should also include an estimate of illegal movements in the outbreak area as well as past movements.

2 **Host** - The species affected and species at risk must be considered. Modeling in the USA suggests that if more than two (2) swine herds are involved at the time of detection, stamping out alone will not be sufficient. Intractability of zoo or exotic livestock must also be considered.
2.1 *Domestic livestock only* - Of the domestic livestock under consideration, swine are crucial because of their ability to amplify the amount of virus that can be spread by airborne means. Sheep and goats tend to be sub clinical and tend to be less likely to spread virus.
Modeling in Australia suggest:

Swine - 100 sows put livestock at risk 10 km downwind
- 1000 swine create a virus plume in 12 hr, infecting livestock over a 200 km^2 area

2.2 *Game farms; zoos*- Are there genetics or endangered species that will not be able to be slaughtered? How effective would quarantine or isolation methods be?
2.3 *Wildlife*-Are there genetics or endangered species that will not be able to be slaughtered? How effective would quarantine or isolation methods be?
2.4 *Virus tropism* - Tropism of the virus is not likely immediately known. By the time it is known, mitigation can be modified but there will not necessarily affect trade. Additional surveillance testing of non-target species will be required.

3 **Status of Outbreak** - estimation of FMD extent and duration of the epidemic. Modeling in the USA suggests that if 5 or more herds are affected with 2 foci separated by 10 km, stamping out alone will not be successful. Sub-factors to be considered include:
3.1 # *affected herds* - A greater number would indicate more undiscovered or incubating herds. This would be of concern in that it could indicate biological terrorism
3.2 # *foci* -One focus of infection would be less likely to spread before stamping out could contain the outbreak. Two 2 or more foci separated by 10 or more kilometers would indicate that the outbreak has already spread
3.2 *Rate of spread* - Rapid spread would be reflected in increasing number of cases per day or increasing number of cases per week. Rate of spread estimates whether in arithmetic (initial) or logarithmic (expansion) portion epidemiological curve

4. **Environment** - includes cultural and physical geography as well as climate.
4.1 *Livestock density and distribution* -How many herds/animals are there per square unit of area? Obviously, the more herds and the more widely distributed they are, the greater the likelihood of spread. Density of livestock and farms are key issues.

4.2 *Livestock management* -Whether the majority of affected producers is large corporations/owners on private land; communes; small producers or back-yard subsistence producers will have an impact on outbreak.
4.3 *Casual access*- Network of transportation corridors in outbreak area with casual human and vehicle traffic.
4.4 *Physical barriers* - Is the outbreak in a naturally isolated area i.e. desert, island/isthmus, rivers, mountains?
4.5 *Climate* - Do prevailing winds, temperature and humidity conditions favor airborne spread

5. **Physical Resources**

5.1 *Slaughter capacity*-FMD infected animals are slaughtered on-farm slaughter by policy. Thus farm technology and mustering facilities, intractability of livestock are factors. If wildlife affected, capability to slaughter all infected animals is very difficult unless confined.
5.2 *Transportation capacity* - If conditions prohibit on-farm disposal, biosecure transportation of carcasses and all animal products or any other such thing used in respect of animals is essential.
5.3 *Disposal capacity* - If on-farm disposal available, heavy equipment would be required for burial or incinerator facilities for burn. If off farm disposal, rendering facilities, burn or burial sites are needed. If these are easily available, then slaughter of animals and disposal of all animal products or any other such thing used in respect of animals is facilitated

6. **Human Resources**

6.1 *Emergency response system /movement control* - Is there sufficient trained staff for stamping out and to enforce movement control restrictions to limit FMD spread. Is the level and quality of surveillance sufficient to effect movement controls? Is the administration able to meet the needs of the emergency response system?
6.2 *Epidemic projections* - potential outcomes for region, species, costs to aid in decision making

7. **Social -Political**

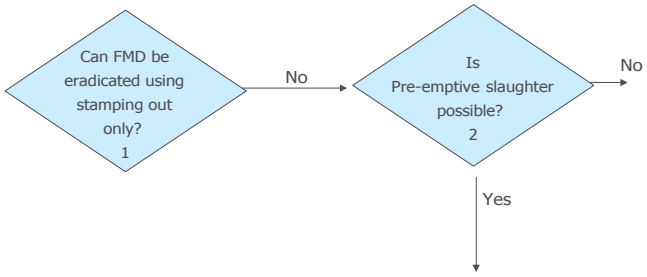
7.1 *Legislation available* - Is there legislation in place for stamping out activities?
7.2 Public *opinion /legislative will/ appearance of government* - What is the current welfare/animal rights climate? What is the public perception of affected animal destruction? What is the public perception that government is acting responsibly? What is the legislative attitude to vaccination, pre- emptive slaughter and compensation?
7.3 *Industry acceptance* - Will the producer organizations concur with the decision? Is information on which tracebacks are based credible? Will industry disclose all traceback information? What is the opinion of non-FMD affected livestock industry sectors? Is the agricultural economy in general affected by international FMD restrictions? What is their opinion?

7.4 *Socio- economic status of producers +/or region.* What is the sophistication of the producers in the affected region? What is their socio-political influence? Are there genetic preservation considerations against stamping out?

8 **Economic**

8.1 *Compensation* - Is there sufficient funding for potential number of animals to be eliminated by stamping out (commercial versus purebred)? Is there compensation for lost production, animal products, by-products etc?
8.2 *Value of exports* - Cost-benefit of country-free status versus stamping out eradication effort. Are there enough funds available for other emergency response activities and supplies?

8.3 *Regionalization* - Ability to regionalize the affected area with international acceptance without eradication of FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions without eradication of FMD in affected area?



Decision Box 2
Is pre-emptive slaughter possible?

In this decision box, only social-political and economic factors must be considered. Of particular importance is the existence of legislation to support pre-emptive slaughter. The issue of adequate resources to perform pre-emptive slaughter at the rate required is dealt with in decision box 3. Pre- emptive slaughter is defined as slaughtering of epidemiologically significant contacts such as known exposed (traceback- includes trace-outs+/- trace ins) herds as well as peripheral herds to an infected herd.

1. **Social-political**

1.1 *Legislation available*-Is there legislation in place for pre-emptive slaughter on traceback and peripheral herds?
1.2 *Public opinion /appearance of government* -What is the current welfare/animal rights climate? Public perception of healthy animal destruction based on risk. What is the public perception that government is acting responsibly?
1.3 *Industry Acceptance* - Will the producer organizations agree to slaughter tracebacks and peripheral herds? Is information on which tracebacks are based credible? Will industry disclose all traceback information? What is the opinion of non-FMD affected livestock industry sectors? Is the agricultural economy in general affected by international FMD restrictions? What is their opinion?

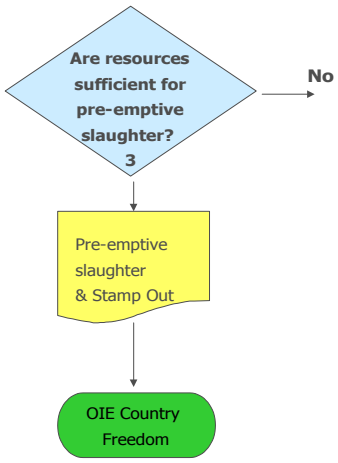
1.4 *Social - economic status of producers/region* - What is t he sophistication of the producers in the affected region? W hat is their social-political influence? Are there genetic p reservation considerations against pre-emptive slaughter?

2 **Economic**

2.1 *Compensation*-Is there sufficient funding for potential n umber of animals to be eliminated by stamping out and pre- emptive slaughter on tracebacks and peripheral herds (commercial / purebred)? Is there compensation for lost production time, animal products, by-products etc? Are animal products (including meat) salvageable for human consumption from pre-emptively slaughtered animals (unknown FMD infection status)?

2.2 *Value of Exports*- Cost-benefit of country-free status versus cost of eradication effort including pre-emptive slaughter costs.

2.3 *Regionalization* - Ability to regionalize the affected area with international acceptance without eradication of FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions without eradication of FMD in affected area?



Decision Box 3
Are resources sufficient for pre-emptive slaughter?

In this third decision box, only resource factors are considered. The social-political and economic considerations are such that pre-emptive slaughter is an option. The prime concern is whether adequate physical and human resources exist to accommodate the anticipated number of livestock to be preemptively slaughtered in addition to those slaughtered under stamping out.

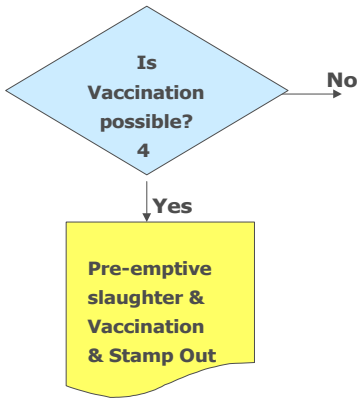
1. **Physical Resources**

1.1 *Slaughter capacity* FMD infected/ high-risk animals should be slaughtered on-farm. Thus farm technology and mustering facilities, intractability of livestock are factors. However, the majority of pre-emptive slaughter would likely be done off farm, as it would be more efficient. The presence of slaughter facilities within the infected zone is important.

1.2 *Transportation capacity* - Unless tested immediately prior to movement, peripheral / traceback herds could be incubating and thus contagious for FMD. If

pre-emptive slaughter is done off farm, biosecure transportation of animals is necessary to prevent spread.
1.3 *Disposal capacity* - If on-farm disposal available, heavy equipment would be required for burial or incinerator facilities for burn. For off farm disposal, rendering facilities, burn or burial sites are needed. If these are easily available, then pre-emptive slaughter and stamping out are good options
1.4 *Time* - Are there sufficient physical resources to permit pre-emptive slaughter of peripheral herds in addition to tracebacks and infected herds before peripheral and traceback herds develop FMD? (Incubation period = 7+/- 4days; OIE= 14 days)

2. **Human Resources**
2.1 *Emergency response system /movement control* - Is there sufficient trained staff for stamping out and pre-emptive slaughter without impacting on enforcement of movement control restrictions to limit FMD spread within the required time frame (see 1.4)? Is the administration able to meet the needs of the emergency response system?
2.2 Epidemic *projections* Potential outcomes including risk of another outbreak with pre- emptive slaughter for region or species and costs to aid in decision-making. Identification of high-risk herds that would have priority for pre-emptive slaughter



Decision Box 4
Is vaccination possible?

In this vaccination decision box, factors surrounding the decision to vaccinate are outlined.

1. **Physical Resources**
1.1 *Vaccine strain available* - Does the NAFMDVB have the correct strain? Does the NAFMDVB have a cross-protection strain available in the bank? (Little or no X-protection between 7 serological types; Field strain may have more than one serotype
1.2 *Vaccine doses available* - Is 2.5 million doses over 21 days sufficient? Doses dispensed @ 300,000 (3d); 700,000 (7d); 1,000,000 (14d); 500,000 (21d). Vaccinate 2X (2-4 wks apart). Single vaccinates disseminate FMD. Booster at 4-12 months.
1.3 *Vaccine logistics* - Are all logistics for vaccination in place i.e. equipment, supplies such as ear tags from NAFMDVB, taggers, record keeping system,

portable corrals, head gates. Has the cold chain provision for the vaccine to the field outbreak center been considered?

1.4 *Vaccine distribution* - Vaccine required for ring vaccination/high risk situations (feedlot or intensive swine) Australian models shows: ring vaccination decreases length of outbreak 0.1- 0.6 weeks; high-risk situation vaccination decreases length of outbreak 1.2 - 2.9 weeks

1.5 *Laboratory capacity*- Does laboratory have diagnostic capability to distinguish vaccinates from infected? Does laboratory have diagnostic capability to analyze suspect and surveillance samples needed to assure trading partners that all animals at risk have been vaccinated? (Outside vaccinated zone at 5% prevalence @ 95% confidence-OIE)

1.6 *Time* - Are there sufficient physical resources to permit vaccination of herds in the affected area prior to spread of infection from the outbreak? (Incubation period = 7+/- 4 d ;OIE =14d); target 85% animals at risk vaccinated in order to prevent spread)

2 **Human Resources**

2.1 *Emergency response system /movement control* - Is there sufficient trained staff for vaccinating including species intractability and numbers (& Pre-emptive Slaughter for both options) and to enforce movement control restrictions to limit FMD spread. Is the administration able to meet the needs of the emergency response system? Are training staff & material available to train vaccination teams? Is competent contract staff available?

2.2 *Risk of FMD introduction* - Risk of vaccinating teams spreading FMD while vaccinating.

2.3 *Epidemic projections*- Potential outcomes including risk of outbreak due to early field challenge or less than 85%coverage in vaccination region. Identify high-risk herds that would seroconvert prior to field virus challenge, cattle (1-2 weeks) and swine (3 weeks). Early field FMD challenge increases FMD carrier state in vaccinated cattle (3 yr), sheep (9 months.), and goats (4 months.).

3 **Social -Political**

3.1 *Legislation available* - Is there legislation required for mandatory vaccination?

3.2 *Public opinion /appearance of government*-What is the current welfare/animal rights climate? What is the public perception of FMD vaccination that could lead to trade restrictions? What is the public perception that government is acting responsibly?

3.3 *Industry acceptance*- Will the producer organizations concur with the vaccination decision? Will industry present all susceptible animals for vaccination? Will industry rather be FMD infected and be compensated at market value or vaccinate and have livestock market value reduced

3.4 *Social- economic status of producers/region* -What is the sophistication of the producers in the affected area? What is their social-political influence?

4 **Economic**

4.1 *Cost of vaccination* - Cost of vaccination requires requesting country to pay $US 400,000 for vaccine finishing to USA plus replacement cost of antigen within 60 days of request. Is this cost prohibitive for a single country?
4.2 *Value of exports* - Does vaccination reduce exportation from the country in general? What is the cost- benefit of additional time to attain country-free status after vaccination? Other vaccinates restrictions (OIE code)?
4.3 *Regionalization - within country/ Tripartite?* - Ability to regionalize the affected area with international acceptance with vaccination for FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions on FMD vaccination?

Decision Box 5
Are resources sufficient for FMD Vaccinate slaughter?

The disposition of vaccinates is a separate consideration from decision to vaccinate but necessary to regain "FMD free without vaccination" status. The main criteria here is the gain of 9 months trade at OIE standards since "FMD free without vaccination" status is achieved 3 months after the slaughter of the last vaccinate where as "FMD free with vaccination" status is achieved 12 months after the last FMD case. However there are international markets whose standards exceed those of OIE (Canada is one of these currently with FMD status without vaccination. Thus, this is primarily an economic consideration but other MITIGATION factors also play a role.

1. **Physical Resources**

1.1 Slaughter *capacity* - Slaughter of FMD vaccinates would likely be done off farm as it would be more efficient but on-farm slaughter may be considered if circumstances warranted. Thus farm technology and mustering facilities, intractability of livestock are factors.
1.2 Disposal *capacity* - If vaccinates are not salvaged for meat or other animal products, on- farm disposal may be considered. What are the requirements for heavy equipment for burial or incinerator facilities for burn? If vaccinates are not salvaged for meat or other animal products, rendering facilities, burn or burial sites must be located.
1.3 *Time* - Are there sufficient physical resources to permit slaughter and disposal of vaccinates within 6 weeks of vaccination (no 2nd dose required)?

2. **Human Resources**

2.1 *Emergency response system /movement control* -Is there sufficient trained staff for slaughter of vaccinates in addition to surveillance activities required for OIE country freedom recognition? Can movement control of vaccinates be tracked to ensure that all vaccinates are slaughtered? Is the administration able to meet the needs of the emergency response system?

2.2 *Epidemic projections* - Potential outcomes including risk of another outbreak once vaccinates eliminated from region.

3. **Social -Political**

3.1 *Legislation available* - Is there legislation for mandatory slaughter of vaccinates?

3.2 *Public opinion /appearance of government* -What is the current welfare/animal rights climate? Public perception of slaughter of healthy FMD vaccinates. What is the public perception that government is acting responsibly?

3.3 *Industry acceptance* - Besides record keeping what are movement restrictions of vaccinates? Will FMD vaccinates be allowed to move (under permit) to other affected tripartite countries? Will the producer organizations concur with the slaughter of vaccinates? Will industry assist in tracking all vaccinates and respect movement controls? (Influenced by 4.2 if the government compensates for loss of market share of vaccinated animals). Will industry agree to slaughter of offspring of vaccinates (maternal antibodies)? What is the opinion of non-FMD affected livestock industry sectors? Is the agricultural economy in general affected by international FMD restrictions? What is their opinion?

3.4 *Social- economic status of producers/region* - What is the sophistication of the producers in the affected area? What is their social -political influence?

4. **Economic**

4.1 *Cost of vaccinate slaughter* - Cost of vaccinate slaughter including tracking of all vaccinates to ensure that all are slaughtered.

4.2 Compensation- Compensation costs for vaccinated animals as well as animal products and by-products, decreased market value of vaccinates, cost of maintenance of vaccinates between vaccination and slaughter? Is compensation funds available in short term to allow rapid slaughter?

3.3 *Value of Exports* - Cost-benefit of country-free status versus cost of compensating for vaccinates until discrimination test of vaccinate versus infected animal is internationally accepted (OIE code)?

4.4 *Regionalization - within country / Tripartite?* Is the ability to regionalize the affected area with international acceptance with vaccination for FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions on FMD vaccination?

Appendix III
Protocol for the North American
Foot and Mouth Disease Vaccine
Bank Vaccination Program 10/18/00

I. Shipment of Vaccine Antigen Concentrate to Contractor

A. Notification

Upon the official declaration of an outbreak of foot and mouth disease by a member country, the Contracting Qfficer's Representative (i.e., the person designated by the Contracting Officer to be responsible for monitoring the performance of work under the contract) will alert the Contractor that finishing of the Vaccine Antigen Concentrate may be required. The Contracting Officer is Mr. Robert Crowther, United States Department of Agriculture, Animal and Plant Health Inspection Service, Minneapolis Business Site, Minneapolis, Minnesota, telephone 612-370-2115. The Contracting Officer's Representative is _____ (vacant), and the Contracting Officer's Technical Representative is _____, and these parties may be reached at the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Foreign Animal Disease and Diagnostic Laboratory, Orient Point, New York, telephone 631-323-3256.

The Contracting Officer's Technical Representative (i.e., the person designated by the Contracting Officer to be responsible for technical review of work under the contract) will convene a conference call with the Chief Veterinary Officers and Chairperson of each country's North American Foot and Mouth Disease Vaccine Bank technical committee to assess the capacity of the Vaccine Antigen Concentrates to protect against the virus type implicated in the disease outbreak.

B. Ordering the Vaccine

If the Chief Veterinary Officer of the infected member country wishes to order the vaccine, that Chief Veterinary Officer will convene a conference call which will include each country's Chief Veterinary Officers to seek their agreement. If more than one member country requests vaccine, allocation of finished product will be based in general upon criteria established in the subject August 24, 2000, Trilateral document. The Chief Veterinary Officers are: Dr. Peter Fernandez, Associate Administrator, United States Department of Agriculture, Animal and Plant Health Inspection Service, Washington, D.C., USA, telephone 202-720-3668; Dr. Brian Evans, Executive Director, Animal Products Directorate, Canadian Food Inspection Agency, Nepean, Ontario, telephone 613 225-2342 ext. 4190; and Dr Angel Omar Flores Hernandez, Director General de Salud Animal, Secretaria de Agricultura, Ganaderia y Desarrollo Rural, Colonia Actipan del Valle, Mexico, telephone 55-34-52-16.

The requesting country's Chief Veterinary Officer will forward the signed permit authorizing importation of the finished vaccine to the Contracting Officer's Representative. The Contracting Officer's Representative will advise the Contracting Officer and the Contractor of the need to activate the contract for finishing the Vaccine Antigen Concentrate into vaccine. The Contracting Officer's Representative will provide the labeling and vaccine shipment information to the Contractor.

C. Transporting the Vaccine Antigen Concentrate

The Contracting Officers Technical Representative will:

- package the antigen in an insulated, cushioned box, with refrigerated ice packs (do not use wet ice or dry ice)
- provide flight information to the Contractor
- prepare an inventory of the Vaccine Antigen Concentrate shipment
- designate a North American Foot and Mouth Disease Vaccine Bank representative to accompany the Vaccine Antigen Concentrate to the Contractor
- provide the Contracting Officer's Representative with a copy of the import permit authorizing entry of the Vaccine Antigen Concentrate into Great Britain

D. Receipt of the Vaccine Antigen Concentrate

The North American Foot and Mouth Disease Vaccine Bank will pay shipping costs and subsequently bill these to the requesting member country. The initial costs borne by the North American Foot and Mouth Disease Vaccine Bank shall be apportioned to recipient countries as agreed to by the commissioners. The North American Foot and Mouth Disease Vaccine Bank and Contractor's representatives will verify the inventory and document the received Vaccine Antigen Concentrate. The Contractor will provide the North American Foot and Mouth Disease Vaccine Bank representative with written receipt of the Vaccine Antigen Concentrate.

II. Shipment of the Vaccine from the Contractor to the Requesting Country

A. Finishing Vaccine

All doses of the selected Vaccine Antigen Concentrate will be finished into vaccine and become the property of the requesting member(s). The North American Foot and Mouth Disease Vaccine Bank- representative will remain at the Contractor's premises until all vaccine has been finished and shipped. Finishing costs (approximately $400,000.00 US) will be paid by the North American Foot and Mouth Disease Vaccine Bank and billed to the receiving member with payment due to the North American Foot and Mouth Disease Vaccine Bank within 30 days (subject to approval by the Commissioners). The Contractor will create an inventory of finished vaccine which will be verified by the North American Foot and Mouth Disease Vaccine Bank representative. The North American Foot and Mouth Disease Vaccine Bank and Contractor representatives, in possession of all documents required for transit of the

finished vaccine, will accompany the vaccine to the airport and will supervise the loading of the vaccine into the aircraft. The North American Foot and Mouth Disease Vaccine Bank will bill the requesting country for the difference in shipping charges between the prescribed destination and the contracted destination. At 7, 14, and 21 days following receipt of the Vaccine Antigen Concentrate by the Contractor, 300,000, 700,000, 1,000,000. and 500,000, respectively, doses of the finished vaccine will be delivered by the Contractor to the recipient.

B. Receipt of Vaccine at Destination

The Contracting Officer's Representative will alert the appropriate veterinary authorities in the receiving country of flight information and they will in turn advise customs officials. Representatives of the receiving country will take possession of the vaccine, verify the inventory of boxes and vials, insure that the emulsion is intact and that the cold chain has been maintained (examine temperature indicator strips)

At the vaccine quarantine site in the receiving country, a representative sample of at least ten smallest-size vials of the finished vaccine arriving from Merial will be selected, packed appropriately with refrigerated ice packs, and then either stored under appropriate conditions in the recipient country or else shipped to the Contracting Officer's Technical Representative for either storage or testing. The number and size of vials selected and serial number will be recorded, and this information, along with the carrier invoice number, shall be reported to the Contracting Officer's Technical Representative. Selection of finished product samples by Merial prior to shipping the vaccine shall be in accordance with the approved contract. Representative of the receiving country will supervise the onward shipping of vaccine in refrigerated vehicles to previously selected strategic locations (as described in each country's Vaccine Usage Guide).

C. Storage and Distribution

Vaccine must be stored at 2 - 8^{o}C with refrigerated ice packs and must not be frozen. When boxes are opened, the temperature indicator strips must be examined to ensure that the cold chain has been maintained. Further distribution must be documented as to volumes and destinations.

D. Application

Each member country should establish a usage plan, including documentation for recording usage. All vaccination personnel must read these instructions. Vaccine must be maintained at 2 - 8^{o}C until the moment of usage. The vaccine is intended for use in sheep, goats, cattle and swine. It is recommended that needles not be reused. Unopened vials brought onto a high risk premises shall be destroyed if not used on that premises. Partially used vaccine vials taken onto the farm shall be destroyed.

Vaccinate all animals over 2 weeks of age with the following dosages:

- cattle and buffalo: 2ml deep intramuscular in the neck
- sheep and goats: I ml intramuscular in the upper neck
- pigs: 2 ml in neck musculature behind the ear

Booster doses, if necessary, should be administered as follows:

- if the vaccine strain virus is homologous with the isolated field strain, re-vaccinate at 6 months post vaccination
- if the vaccine strain is heterologous to the isolated field strain but considered to be protective against the isolated field strain, re-vaccinate at 4-6 weeks and again at 6 months post-vaccination

E. Identification of Vaccinates

Refer to the "Proposed Protocol for the Identification of Foot and Mouth Disease Vaccinated Animals Through Final Disposition," a report of the Trilateral Foot and Mouth Disease Animal Identification Working Group, August 22-23, 2000, regarding identification and record keeping of foot and mouth disease vaccinated animals. Records should be kept electronically. Vaccinated animals may be euthanized on the affected premises or other approved location, shipped to slaughter for human consumption following the 60 day post-vaccination oil adjuvant associated withdrawal period, or entered into the general animal population after an acceptable level of risk is determined.

F. Movement of vaccinates and products of vaccinated animals

Movements of vaccinates and products harvested from vaccinates (excluding semen and embryos) will follow standards in the Office International des Epizooties International Animal Health Code. Animals vaccinated during the campaign may be eligible for export to other member countries if these animals can be acceptably demonstrated to not having been infected with the foot and mouth disease virus. These conditions apply only if all vaccinates are ear tagged, movement of vaccinates remain under veterinary service control until death, and an active program of slaughter of vaccinates is followed. Otherwise no movement will be permitted.

Appendix IV
European Union Document
on FMD Control and Eradication
(from the Official Journal of the
European Communities
March 31, 2001

COMMISSION DECISION of 30 March 2001 laying down the conditions for the control and eradication of foot-and-mouth disease in the United Kingdom in application of Article 13 of Directive 85/511/EEC

(notified under document number C(2001) 1041)

(Text with EEA relevance)

(2001/257/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (1), as last amended by Directive 92/118/EEC (2), and in particular Article 10 thereof,

Having regard to Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease (3), as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 13(3) thereof,

Whereas:

(1) The control measures for foot-and-mouth disease laid down in Directive 85/511/EEC are aimed at eradicating the disease as quickly as possible by stamping out of infected, contaminated or in-contact herds, applying strict movement controls on animals of susceptible species and products derived from such animals and surveillance in the affected area to substantiate prior to lifting the control measures the absence of virus circulation.

(2) However, in Article 13(3) of Directive 85/511/EEC provisions are made for emergency vaccination where the disease expands.

(3) The principles provided for in this Article require to balance the decision on resorting to vaccination against basic Community interests which must not be endangered.

(4) Following the reports of outbreaks of foot-and-mouth disease in the United Kingdom, France, the Netherlands and Ireland, the Commission adopted Decisions 2001/172/EC (4), 2001/208/EC (5), 2001/223/EC (6) and 2001/234/EC (7) concerning certain protection measures with regard to foot-and-mouth disease in the respective Member State.

(5) In addition to the measures within the framework of Directive 85/511/EEC, the United Kingdom apply the pre-emptive killing of susceptible animals in holdings situated in close proximity to infected or suspect holdings,

taking into account the epidemiological situation, the high density of susceptible animals in certain parts of the territory and the poor expression of clinical signs in certain susceptible species.

(6) Killing of animals for disease reasons must be carried out in accordance with Council Directive 93/119/EEC of 22 December 1993 on the protection of animals at the time of slaughter or killing (8).

(7) Large scale killing of animals of infected or contaminated holdings may quickly exhaust the capacities for safe destruction of carcasses and thereby unavoidably delay the pre-emptive killing and this may lead to the amplification and spread of the virus.

(8) The competent authorities of the United Kingdom have presented to the Commission a programme to employ protective vaccination in bovine animals under certain clearly defined conditions as an additional instrument to control and eradicate foot-and-mouth disease in connection with the pre-emptive killing of animals of other susceptible species in defined densely populated livestock areas.

(9) In its report of 10 March 1999 the Scientific Committee on Animal Health and Animal Welfare made recommendations on the strategy for emergency vaccination against foot-and-mouth disease, which must be taken into account (9).

(10) Recourse to any kind of vaccination will inevitably jeopardise the foot-and-mouth disease status in terms of international trade not only for the Member State or part of its territory where vaccination is carried out.

(11) The Commission prior to taking a Decision on emergency vaccination must ensure that the measures to be taken include at least those provided for in Article 13(3) first to sixth indent of Directive 85/511/EEC.

(1) OJ L 224, 18.8.1990, p. 29.
(2) OJ L 62, 15.3.1993, p. 49.
(3) OJ L 315, 26.11.1985, p. 11.
(4) OJ L 62, 2.3.2001, p. 22.
(5) OJ L 73, 15.3.2001, p. 38.
(6) OJ L 82, 22.3.2001, p. 29. (8) OJ L 340, 31.12.1993, p. 21.
(7) OJ L 84, 23.3.2001, p. 62. (9) http://europa.eu.int/comm/food/fs/sc/scah/outcome_en.html

(12) It is the purpose of this Decision to define the conditions under which the United Kingdom may apply emergency vaccination and to outline the follow-up measures applicable to vaccinated animals and products derived from such animals.

(13) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

For the purpose of this Decision the following definitions shall apply:

1. ‘Pre-emptive killing’ shall mean the killing of susceptible animals on holdings within a certain radius around holdings placed under the restrictions laid down in Articles 4 or 5 of Directive 85/511/EEC.

It is aimed at the urgent reduction of numbers of animals of susceptible species in an infected area.

2. ‘Protective vaccination’ shall mean emergency vaccination of bovine animals in identified holdings situated in a defined area, the ‘vaccination zone’, which is carried out exclusively in conjunction with pre-emptive killing of certain categories of sheep and other animals of susceptible species as defined in paragraph 1.
It is aimed at an urgent reduction of the amount of virus circulating and the risk of virus spreading beyond the perimeters of the area, and is subjected to the condition that such vaccinated animals are not subject to pre-emptive killing.
Article 2
1. Without prejudice to Directive 85/511/EEC, and in particular Articles 4, 5 and 9 thereof, and without prejudice to Decision 2001/172/EC, the United Kingdom may decide on resorting to protective vaccination under the conditions set out in Annex I.
2. Before commencing the measures referred to in paragraph 1, the United Kingdom shall ensure that the Member States and the Commission are officially and fully informed on the details concerning the geographical and administrative definition of the vaccination zone, the number of holdings affected, the time when vaccination will be started and accomplished, and of the circumstances motivating the decision to implement the measures.
Subsequently the United Kingdom shall ensure that the information submitted in accordance with the first subparagraph is completed and updated without undue delay, in particular with regard to the details concerning the number of holdings and animals affected, and the modifications of the restrictions applied in the areas concerned.
Article 3
This Decision is addressed to the Member States.
Done at Brussels, 30 March 2001.
For the Commission
David BYRNE
Member of the Commission
EN Official Journal of the European Communities 31.3.2001 L 91/100
ANNEX I
Conditions for the use of protective vaccination in the control and eradication of foot-and-mouth disease in application of Article 13(3) of Directive 85/511/EEC
1. Extent of the geographical area in which protective vaccination is to be carried out
The vaccination zone shall be within an area defined in Annex II.
The restrictions applicable in the vaccination zone shall be those in Annex III of this Decision, without prejudice to the provisions in Article 9 of Directive 85/511/EEC.
2. Species and age of the animals to be vaccinated All bovine animals over 1 week of age independently of their sex and gestational or productive status.
3. Duration of the vaccination campaign The vaccination campaign shall be completed within 14 days.
4. Specific standstill of vaccinated animals and products of vaccinated animals
Measures laid down in Annex III and the treatments of products derived from vaccinated bovine animals as laid down in Annexes IV, V, VI-A and VI-B.
5. Special identification and special registration of the vaccinated animals
— Identification of all bovine animals in accordance with Regulation (EC) No 1760/2000 (OJ L 204, 11.8.2000, p. 1),
— on the spot ear-tagging of calves less than 20 days of age and application of an indelible mark with subsequent issuing of passport,

— marking of vaccination status in the passport,
— entering vaccination details in the database established in accordance with Regulation (EC) No 1760/2000
6. Other matters appropriate to the protective vaccination
6.1. Adjustment of zones established in accordance with Article 9 of Directive 85/511/EEC
A surveillance zone of at least 10 km around the vaccination zone referred to in point 1.
6.2. Period for which the measures applied in the zones established in accordance with Article 9 of Directive 85/511/EEC are maintained
Without prejudice to the provisions in Article 9 of Directive 85/511/EEC and of Commission Decision 2001/172/EC the measures applied in the vaccination zone must remain in force until the measures are lifted in accordance with point 6.6.
6.3. Execution of the vaccination campaign Vaccination must be carried out under the direction of a veterinary surgeon of the competent authorities. Necessary measures must be in place to avoid possible spread of virus. Any residual quantities of vaccine must be returned to the point of vaccine distribution with a written record on number of animals vaccinated and the number of doses used.
6.4. Vaccine to be used The inactivated vaccine of at least 100 PD_{50} to be used must be suitably formulated for the species concerned and be effective against the virus type circulating. It shall be used in accordance with the instructions of the manufacturer.
6.5. Information on implementation of this programme to the Commission
A detailed report on the execution of the programme shall be provided to the Commission and the Member States in the framework of a Standing Veterinary Committee before the lifting of the restrictions referred to in points 6.1 and 6.2.
6.6. Lifting of restrictions In accordance with Article 16 of Directive 85/511/EEC and not earlier than 12 months after the completion of the measures in point 3 and not earlier than 12 months after the last outbreak in the vaccination zone, whichever is the latest.
ANNEX II
Vaccination zone:
Administrative areas in the counties of Cumbria and Devon in Great Britain.
EN Official Journal of the European Communities 31.3.2001 L 91/101
ANNEX III
MEASURES APPLICABLE IN THE VACCINATION ZONE
1. The United Kingdom shall ensure that the following measures are applied in the vaccination zone during the period from the beginning of the vaccination until at least 30 days have elapsed following the completion of the vaccination:
(a) Movement of live vaccinated bovine animals is prohibited within and out of the vaccination zone.
Derogating from the prohibition above and after clinical inspection of the animals in question and of the herds of origin or dispatch, the competent authorities may authorise the direct transport of live bovine animals species for immediate slaughter in a slaughterhouse designated by the competent authority and situated within the vaccination zone or in exceptional circumstances to be authorised on a case by case basis by the competent authorities preferably close to that zone.
(b) Fresh meat produced from vaccinated animals slaughtered during the period referred to in this paragraph shall bear the stamp provided for in Article 5a of Directive 72/461/EEC, shall be stored and transported separately from meat not bearing the said stamp, and shall subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with Annex IV.
(c) Milk and milk products produced from vaccinated animals during the period referred to in this paragraph may be placed on the market within or out of the vaccination zone, provided that at least one of the treatments referred to in Annexes VI-A and VI-B has been applied in an establishment located in the vaccination zone or, in exceptional circumstances to be authorised on a case by case basis by the competent authorities outside that zone. This treatment shall be certified by the competent veterinary authorities.
(d) The collection of semen for artificial insemination from male bovine animals kept in centres situated within the vaccination zone shall be suspended.
Derogating from the prohibition above, the competent authorities may authorise the collection of semen from male bovine animals for the production of frozen semen to be used within the vaccination zone at semen collection centres within the vaccination zone, if it is ensured that the semen collected during that period is stored separately for at least 30 days and is dispatched only after the following measures have been taken:

the donor males have been vaccinated following a negative test for antibodies against foot-and-mouth disease virus
undertaken prior to vaccination, and
a negative result has been achieved in all susceptible animals present at the time on the semen collection centre, in a
virus isolation test or in an approved test for antibody against non-structural proteins carried out at end of the quarantine period for the semen.
(e) Collection of ova and embryos from donor female bovines shall be prohibited.
2. The United Kingdom shall ensure that the following measures are applied in the vaccination zone after the completion
of the measures laid down in paragraph 1 and until the restrictions on the vaccination zone are lifted:
(a) Intra-Community trade in bovine animals seropositive against foot-and-mouth disease is prohibited.
(b) Intra-Community trade in semen, ova and embryos of bovine animals vaccinated against foot-and-mouth disease is
prohibited.
(c) Collection of ova shall be prohibited.
(d) Movement of bovine animals may only take place under the following conditions:
Movement out of the vaccination zone of non-vaccinated bovine animals other than those referred to in point (3) below may be authorised not earlier than 3 months after completion of all vaccination and in accordance with Directive 85/511/EEC.
Derogating from the provisions in the first subparagraph above, the United Kingdom may authorise the transport of non-vaccinated bovine animals to a slaughterhouse outside the vaccination zone for immediate slaughter, provided that the meat shall be subjected to the treatment in Annex V.
Movement out of the vaccination zone of vaccinated bovine animals shall be prohibited, unless 12 months have elapsed after the completion of the measures referred to in paragraph 1 and not earlier than 12 months after the last
outbreak in the zone, whichever is the latest.
Derogating from the provisions in the first subparagraph, the United Kingdom may authorise the transport of vaccinated bovine animals to a designated slaughterhouse outside the vaccination zone for direct slaughter, provided
that the meat shall be subjected to the treatment in Annex V.

Non-vaccinated offspring of vaccinated dams, shall be prohibited from leaving the holding of origin unless being transported to:
either a slaughterhouse for immediate slaughter, the meat being subject to the treatment in Annex V, or
to another holding within the vaccination zone, or
any holding after obtaining a negative result in a serological test for the detection of antibody against the foot-andmouth
disease virus.
(e) The restrictions applied to fresh meat produced from vaccinated animals of susceptible species as laid down in Annex V, and to meat products as laid down in Annex VI, shall continue to apply until the restrictions on movements of vaccinated animals of susceptible species have been lifted in accordance with Article 16 of Directive 85/511/EEC, and in any case not earlier than 12 months after the completion of vaccination and 12 months after the last outbreak in the vaccination zone whichever is the latest.
(f) The restrictions applied to fresh milk produced from vaccinated animals of susceptible species and to milk products produced from such milk as laid down in Annexes VI-A and VI-B shall continue to apply until the restrictions on movements of vaccinated animals of susceptible species have been lifted in accordance with Article 16 of Directive 85/511/EEC, and in any case not earlier than 12 months after the completion of vaccination and 12 months after the last outbreak in the vaccination zone whichever is the latest.
Treatment Food-and-mouth disease
ANNEX IV
TREATMENT OF MEAT TO ENSURE DESTRUCTION OF FOOT-AND-MOUTH DISEASE VIRUS
(a) Heat treatment in a hermetically sealed container with an F_0 value of 3,00 or more +
(b) Heat treatment at a minimum temperature of 70 °C, which must be reached
throughout the meat
+
(c) Heat treatment in a hermetically sealed container to at least 60 °C for a minimum of
4 hours, during which time the core temperature must be at least 70 °C for 30
minutes
+
(d) Natur fermentation and maturation of not less than 9 months for boneless meat,
resulting in the following characteristics: aw value of not more than 0,93 and a pH
value of not more than 6,0
+
(e) As (d) above but meat may contain bone. All the necessary measures must be taken
to avoid cross contamination

+
(f) Heat treatment ensuring a core temperature of at least 65 °C is reached for the time necessary to achieve a pasteurisation value (pv) equal to or more than 40
+
'+': Effectiveness recognised
EN Official Journal of the European Communities 31.3.2001 L 91/103
ANNEX V
TREATMENT OF FRESH MEAT
1. De-boned fresh meat:
Meat as described in Article 2(a) of Council Directive 64/433/EEC together with diaphragms but excluding offal, from
which the bone and the main accessible lymphatic glands have been removed.
2. Trimmed offal:
— heart from which lymphatic glands, connective tissue and adhering fat have been completely removed,
— liver from which lymphatic glands, adhering connective tissue and fat have been completely removed,
— whole masseter muscles, incised in accordance with paragraph 41 (A)(a) of Chapter VIII of Annex I to Directive 64/433/EEC, from which lymphatic glands, connective tissue and adhering fat have been completely removed,
— tongues with epithelium and without bone, cartilage and tonsils,
— lungs from which the trachea and main bronchi and the mediastinal and bronchial lymphatic glands have been removed,
— other offal without bone or cartilage from which lymphatic glands, connective tissue, adhering fat and mucous membrane have been completely removed.
3. Maturation
— maturation of carcasses at a temperature of more than + 2 °C for at least 24 hours,
— pH value in the middle of *Longissimus dorsi* muscle recorded as less than 6.0.
4. Effective measures must be applied to avoid cross contamination.
EN Official Journal of the European Communities 31.3.2001 L 91/104
ANNEX VI-A
TREATMENT OF MILK TO ENSURE DESTRUCTION OF FOOT-AND-MOUTH VIRUS IN MILK FOR HUMAN CONSUMPTION
Treatment of milk must be carried out in accordance with paragraph 1 below and in any case necessary precautions must
be taken to avoid contact of the milk or milk products with any potential source of foot-and-mouth virus after processing.
1. Milk for human consumption must be subject to at least one of the following treatments:
1.1. sterilisation at a level of at least $F_0$3,
1.2. single UHT ($_1$) treatment,
1.3. double HTST ($_2$) treatment of milk with a pH above 7,0,
1.4. single HTST treatment of milk with a pH less than 7,0,
1.5. single HTST combined with another physical treatment by:
1.5.1. either a second heat treatment resulting in a negative reaction to the peroxidase test,
1.5.2. or lowering the pH < 6 for at least one hour,
1.5.3. or additional heating to 72 °C or more, combined with desiccation.
2. Milk based products must be produced from milk after the treatment referred to in paragraph 1.
($_1$) UHT = Ultra High Temperature treatment at 130 °C for 2-3 sec.
($_2$) HTST = High Temperature Short Time pasteurisation at 72 °C for 15-17sec or equivalent pasteurisation effect achieving a negative
reaction to a phosphatase test.
EN Official Journal of the European Communities 31.3.2001 L 91/105
ANNEX VI-B
TREATMENT OF MILK TO ENSURE DESTRUCTION OF FOOT-AND-MOUTH VIRUS IN MILK NOT INTENDED FOR HUMAN CONSUMPTION AND IN MILK FOR ANIMAL CONSUMPTION
Treatment of milk and milk-based products must be carried out in accordance with paragraphs 1 to 3 below depending
on the intended use of the milk or milk-based products, and in any case necessary precautions must be taken to avoid
contact of the milk or milk based products with any potential source of foot-and-mouth virus after processing.
1. Milk not intended for human consumption and milk intended for animal consumption must be subject to at least one of the following treatments:
1.1. sterilisation at a level of at least $F_0$3,
1.2. single UHT ($_1$) combined with another physical treatment referred to in either paragraph 1.4.1. or 1.4.2.
1.3. double HTST ($_2$),
1.4. single HTST combined with another physical treatment by
1.4.1. either lowering the pH < 6 for at least one hour,
1.4.2. or additional heating to 72 °C or more, combined with desiccation.
2. Milk-based products not intended for human consumption must be produced from milk after the treatments

referred to in paragraph 1.
3. Milk-based products intended for animal consumption must be produced from milk after one of the treatments referred to in paragraph 1.1., 1.2. and 1.4.
4. Whey to be fed to pigs and produced from milk treated as described in paragraph 1 must be collected at least 16 hours after milk clotting and its pH must be recorded as <6,0 before transport to pig holdings.
(1) UHT = Ultra High Temperature treatment at 130 °C for 2-3 sec.
(2) HTST = High Temperature Short Time pasteurisation at 72 °C for 15-17sec or equivalent pasteurisation effect achieving a negative
reaction to a phosphatase test.

Appendix V
FMD Vaccine Package Insert, FMD Vaccine, North American Foot and Mouth Disease Vaccine Bank

Foot and Mouth Disease Vaccine
Serotype _____ , Killed virus

The use of this product is restricted to veterinarians accredited under the Regulatory Authorities of the respective country as prescribed in their Emergency Disease Control Program in the event of a threat or the occurrence of a foot and mouth disease outbreak.

Composition: Inactivated foot and mouth disease virus containing one serotype or more with a double oil adjuvant.

Direction:

1. Primary vaccination:

☒ Cattle and swine: 2 ml intramuscularly.

• Small ruminants: 1 ml intramuscularly.

2. Secondary vaccination:

☒ Proceed as directed by the Regulatory Authorities of the respective country.

Precautions:

1. Only vaccinate healthy animals.
2. Store at 2^{o}-7^{o}C and protect from light. Do not freeze.
3. Use entire contents when first opened. Use sterilized syringes and needle to administer this vaccine. Dispose of syringes, needles, containers, and unused vaccine in accordance with directions from the National regulatory authorities.
4. Do not vaccinate within 60 days prior to slaughter.
5. Vaccination may be followed by a small local swelling and/or pyrexia, both of short duration.
6. As with many vaccines, anaphylaxis may occur after use. The use of epinephrine is recommended followed with appropriate supportive therapy.
7. This vaccine contains an oil emulsion adjuvant. In case of accidental human injection, seek medical assistance immediately.

This product has been prepared for the North American Foot and Mouth Disease Vaccine Bank

Tables and Figures

Note: In the case of AFTOPOR vaccination of pigs, it is recommended that sows be given a booster vaccination 1 month before farrowing regardless of the epidemiological status of the region.

Figure 1. Vaccination Center Communications

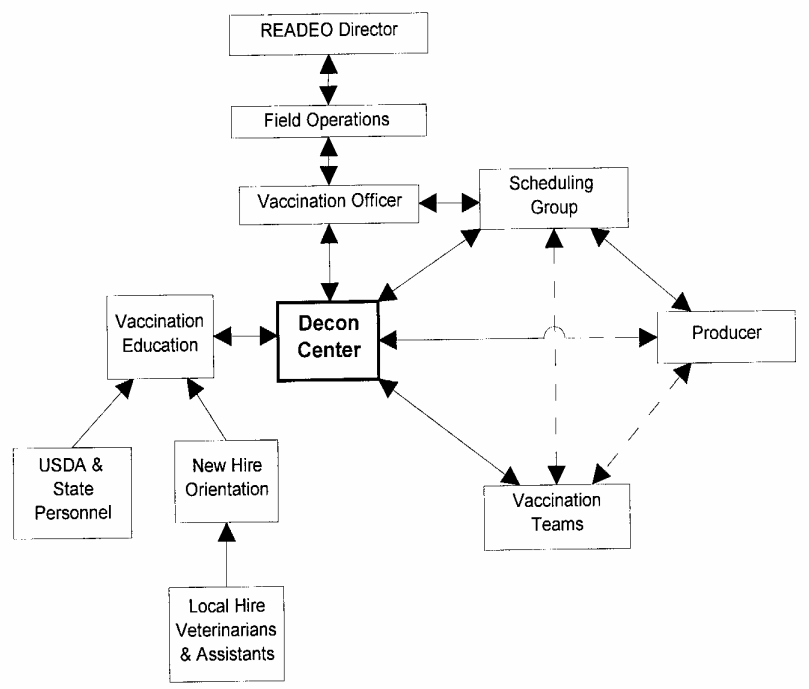


Figure 2. Correct Insertion of the Air-bleed and Vaccine Withdrawal Needles.

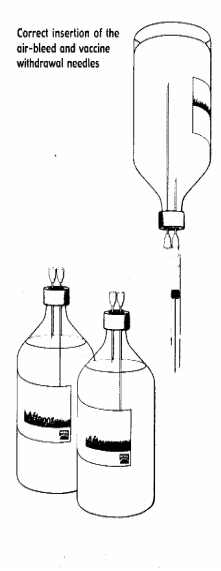


Figure 3. Recommended Animal Injection Sites.

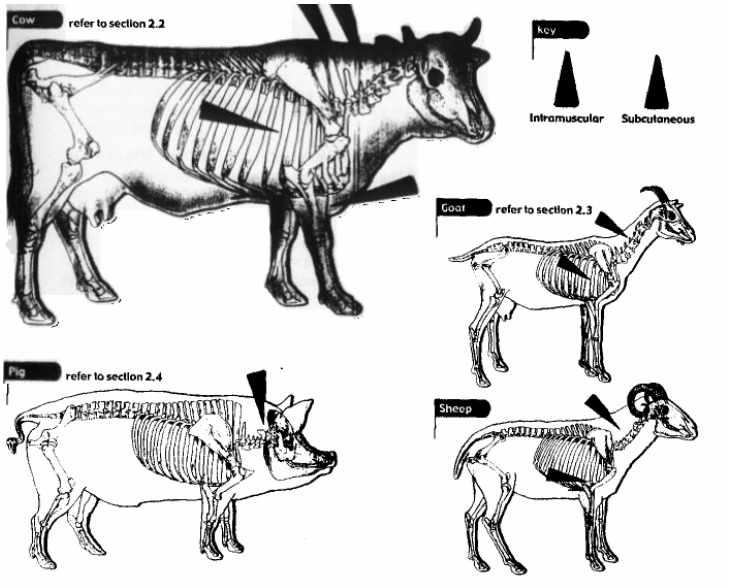


Table 1. Vaccine Shipping Dates, Doses, and Required Storage Space. **(Editor's note: Delete this table because of confidentiality issues?)**

	Total Doses	Total Storage Volume
Shipped on day 3	xxxx	xxx ft3
Shipped on day 7	xxxx	xxx ft3
Shipped on day 14	xxxx	xxx ft3
Shipped on day 21	xxxx	xxx ft3
Total:		

Note: **This is confidential information, not to be disseminated openly.**

Table 2. Recommended Revaccination for Low-Risk Areas.

	From Non-Vacc Dams ***Start Vacc at 14 days old (2 wks)***	**From Vacc Dams** ***Start Vacc at 2 ½ mo (10 wks)***
Pigs, Sheep, and Goats	▪ 1 vacc If kept beyond 6 mo: ▪ 2 vacc, 4-5 wks apart ▪ Revacc every 6 mo ▪ From 1 yr of age, revacc annually	▪ 1 vacc If kept beyond 6 mo: ▪ 2 vacc, 4-5 wks apart ▪ Revacc every 6 mo ▪ From 1 yr of age, revacc annually
Cattle	▪ 2 vacc, 4-5 wks apart ▪ Revacc every 6 mo	▪ 2 vacc, 4-5 wks apart ▪ Revacc every 6 mo

Table 3. Recommended Revaccination for High-Risk Areas.

	From Non-Vacc Dams ***Start Vacc at 14 days old (2 wks)***	**From Vacc Dams** ***Start Vacc at 2 ½ mo (10 wks)***
All Animals	▪ 2 vacc, 4-5 wks apart	▪ 2 vacc, 4-5 wks apart
Cattle and Pigs	▪ Revacc every 4 mo.	▪ Revacc every 4 mo.
Sheep and Goats	▪ Revacc every 6 mo.	▪ Revacc every 6 mo.